AstraZeneca

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Implementation of the US PRECISION AIRQ™, Asthma Checklist, and Educational Resources (PRECISION Program) into Clinical Practice Using Telehealth and In-Person Platforms

Sponsor:	AstraZeneca Pharmaceuticals, LP
Author:	AZ PRECISION Team PPD PPD 1800 Concord Pike Wilmington, DE 19803 PPD PPD

TABLE OF CONTENTS PAGE

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation or special term	Explanation
ACE	Asthma Clinic Experience Questionnaire
CCI	
AE	Adverse event
AIRQ™	Asthma Impairment and Risk Questionnaire
CFR	Code of Federal Regulations
CI	Confidence interval
CRF	Case Report Form
ePRO	Electronic patient-reported outcome
ED	Emergency department
FDA	Food and Drug Administration
FQHC	Federally qualified health care
GCP	Good Clinical Practice
GINA	Global Initiative for Asthma
HCP	Healthcare practitioner
HIPAA	Health Insurance Portability and Accountability Act
HRQOL	Health-related quality of life
ICH	International Council for Harmonisation
ID	Identification
IEC	Independent ethics committee
IRB	Institutional review board
NAEPP	National Asthma Education and Prevention Program
OCR	Optical character recognition
OCS	Oral corticosteroids
CCI	CCI
PCP	Primary care provider
ROC	Receiver operating characteristic
SD	Standard deviation
SOP	Standard operating procedure
SUA	Severe uncontrolled asthma
US	United States

RESPONSIBLE PARTIES

Name	Professional Title	Role in Study	Affiliation	E-mail Address
PPD	PPD –	Co-Team Lead	AstraZeneca	PPD
PPD	PPD	Medical Lead	AstraZeneca	PPD
PPD	PPD	Study Lead	AstraZeneca	PPD
PPD	PPD	Statistician	AstraZeneca	PPD
PPD	PPD	Co-Principal Investigator	Evidera	PPD
PPD	PPD	Co-Principal Investigator	Evidera	PPD
PPD	PPD	Project Manager	Evidera	PPD

PROTOCOL SYNOPSIS

Implementation of the US PRECISION AIRQ™, the Asthma Checklist, and Educational Resources (PRECISION Program) into Clinical Practice using Telehealth and In-Person Platforms

Background/Rationale: The AstraZeneca US PRECISION initiative formed an advisor network of scientific and clinical experts and healthcare practitioners (HCP) to develop a point-of-care tool—the Asthma Impairment and Risk Questionnaire™ (AIRQ™)—for the identification of patients at risk for adverse outcomes from uncontrolled asthma. To date, the AIRQ™ has been qualitatively evaluated among patients in an interview setting to ensure that it is understandable and easy to complete and the feasibility of implementing the AIRQ™ into a variety of clinical practices (i.e. allergy, pulmonary and primary care) was evaluated in a pilot program that was well-received by patients and demonstrated the ease of use by clinical staff. A cross-sectional validation study was conducted that demonstrated the validity of the AIRQ™ relative to a composite of Asthma Control Test™ (ACT™) score plus medical-record documented prior-year exacerbations to derive the final AIRQ™ items, scoring and cut points for levels of asthma control (Murphy et al. 2020). The final AIRQ™ consists of 10 yes/no items with the total score used to identify patients at risk for poor asthma outcomes.

This study aims to evaluate the implementation of the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) in clinical practice using telehealth and in-person platforms.

Objectives and Hypotheses:

The primary objective of this study is:

1. To assess the process (ease of use and challenges to HCPs and patients) and potential benefits (ability to capture and take action to remediate previously unrecognized morbidity) of implementing the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) into clinical practice during telehealth and in-person visits.

The secondary objectives of this study are:

1. To assess asthma patients' clinic visit experiences when the AIRQ™, the Asthma Checklist, and educational resources (PRECISION program) are utilized as part of a telehealth or in-person visit with their HCP;

2. To explore change in AIRQ™ scores from the initial visit to follow-up visit(s) (when available).

The following are exploratory objectives:

1. CCI [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

This study is descriptive and there will be no formal hypothesis testing for the primary objective.

Methods:

Study design: This community program intervention study will examine the process of integrating the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) into clinical practice using either in-person or telehealth visits. Providers use of patients' responses to the AIRQ™, Asthma Checklist, and educational resources to guide treatment and asthma work-up and management also will be examined. The study duration is 12-months, with study enrollment lasting nine (9) months for each site (implementation stage), and an additional three (3) months of follow-up to assess the sustainability of using the PRECISION

program in clinical practice (sustainability stage). The nine-month implementation stage will allow for the recruitment of approximately 50 patients at each site for an initial study visit, plus the potential for follow-up visit(s). The three-month sustainability stage will allow for sites to continue to implement the PRECISION program in their clinical practice and for sites to describe any continued benefits of using the PRECISION program at their site.

Approximately fifteen (15) to twenty (20) clinical sites will be recruited to participate in this study, categorized into the following three practice clusters: (1) primary care site (e.g., private practice, FQHC; (2) specialty care site (pulmonary, asthma/immunology); and (3) novel sites (e.g., pharmacy, nurse practitioners, nurse educators, prescribers and Non-prescribers, telehealth component of Allergy and Asthma Network). While all sites will be able to conduct both in-person and telehealth visits, sites will aim to conduct a minimum of approximately 25% of their initial patient visit using a telehealth platform. Both platforms (in-person and telehealth) can be used for the follow-up visit(s) for all practice types.

During the clinic visit (telehealth or in-person), HCPs will assess the patients' responses to the AIRQ™ questions, discuss the results with the patient, and use the Assess component of the Asthma Checklist (as appropriate per HCP judgment). Before completing the initial study visit, patients will be asked if they would be willing to complete additional questions and, for those who agree, sites will send them an electronic survey link (via YouGov) which will include the following questionnaires: the Asthma Clinic Experience (ACE) Questionnaire, CCI and a Patient Sociodemographics Questionnaire. If a follow-up visit (telehealth or in-person) is conducted during the follow-up period, the clinical site will administer the AIRQ™ 3-month recall version (regardless of timing of follow-up visit). Sites/HCPs will complete a Clinical Case Report Form (CRF) after the initial visit and after the follow-up visit (if conducted) for each participant. It should be noted that for all visits (initial and follow up), HCPs will be required to review the Assess component of the Asthma Checklist and provide their responses on the CRF; the Adjust and Review components of the Asthma Checklist will be available, along with the other PRECISION resources, on the study website as well, but will not be mandatory to complete. CCI

Additionally, Evidera will host a 30-minute conference call with each clinical site for up to four (4) time points (touchpoints) to discuss the implementation of PRECISION tools (i.e., frequency of visits to and the number of PDF views from study website), assess whether sites are meeting their targets for using the telehealth platform, address site questions, and discuss any challenges of implementing the PRECISION program. These meetings will take place at Months 1, 2, 3 (optional), and 6 and will also be used to identify any sites that may benefit from participating in a re-training session. The optional Month 3 touchpoint will be based on whether the site is having any difficulties with the study.

Study Population: Clinic staff will invite patients age ≥13 years with HCP-confirmed asthma diagnosis who are presenting for a clinic visit (telehealth or in-person) to complete the AIRQ™ and participant questionnaires. Each site will aim to recruit approximately 50 patients with a total sample size ranging from approximately 750 to 1,500 patients.

Inclusions Criteria:

Patients must meet all of the following criteria to be eligible for enrollment:

1. ≥ 13 years of age at the time of enrollment
2. Prior diagnosis of HCP confirmed asthma
3. Able to read, understand, and speak English or Spanish sufficiently to self-complete or be administered the AIRQ™ via telephone, desktop computer, or mobile device (e.g., smartphone, iPad)
4. Provide consent (adults/parents/guardians) and assent (age 13-17 years) to participate in the study

Exclusion Criteria:

Patients meeting any of the following criteria will not be included in the study:

1. Current diagnosis of active COPD or any lower respiratory diagnosis other than asthma.
2. Has a cognitive impairment, hearing difficulty, acute psychopathology, medical condition, or insufficient knowledge of the English or Spanish language that, in the opinion of the investigator, would interfere with his or her ability to agree to participate and/or complete the AIRQ™ or other study questionnaires.

Data Source(s): Approximately fifteen (15) to twenty (20) clinical sites will be selected to implement the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) into clinical practice using telehealth and in-person platforms. The sites will be selected based on the site principal investigator's experience and qualifications, use of a telehealth platform as part of their care practice, the number of asthma patients visiting the clinic via telehealth per week, the diversity of the asthma patients treated by the clinic, the ability of the site to complete the study tasks in the allotted timeframe, and the anticipated unique component(s) used to contribute to the implementation process by the study site. Each site will be responsible for recruiting approximately 50 asthma patients per site.

Exposure(s):

Patients will complete the following measures:

- AIRQ™ 12-month
- AIRQ™ 3-month Recall (as appropriate)
- ACE Questionnaire (for those who agree; initial visit only)
- [redacted]
- [redacted]
- Patient Sociodemographics Questionnaire (for those who agree; initial visit only)

HCPs will complete the following measures:

- Clinical Case Report Form (CRF)
- Follow-up Clinical CRF (if appropriate)
- Clinal Site Touchpoint Questions (via telephone)
- Post-study Survey
- Qualitative Interview
- 12-Month Post-Initial Visit Exacerbation CRF (when applicable)

Outcome(s):

- Qualitative interview responses
- Post-study Survey responses
- Touchpoint findings
- ACE Questionnaire responses
- [redacted]
- CCI [redacted]
- Relationship between HCP actions (e.g. step up/step down/no change in therapy, referral to specialist, initiation of biologic) based on assessment component of Asthma Checklist and AIRQ^{TM} scores
- AIRQ™ change scores (when available)
- CCI [redacted]

Sample Size Estimations: As the primary aim of this study is to assess the process and feasibility of implementing the AIRQ™, Asthma Checklist, and education resources (PRECISION program) using a telehealth or in-person platform, inferential statistics will not be conducted as part of the primary endpoint, and a formal sample size estimation is not applicable. Each site will target approximately 50 patients with asthma. Implementing the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) among approximately 50 patients per site will provide sites with enough experience to provide feedback on the outcomes, barriers, benefits, challenges, ease of implementation, and areas for improvement for future integration as a telehealth platform.

Statistical Analysis: Descriptive statistics (n, frequency, mean, SD) will be used to characterize the sample in terms of sociodemographic and clinical characteristics. The sociodemographic and clinical characteristics will be summarized for the sample overall as well as for each site and cluster. Descriptive statistics (n, frequency, mean, SD) will also be used to summarize the actions of HCPs (e.g., actions accessed/taken, step up/step down/no change in therapy, referral to a specialist, initiation of biologics), results from the HCP's responses on the Post-study Survey, patients' responses to the ACE Questionnaire and the [redacted], AIRQ™ scores, CCI [redacted]

CCI The relationships between AIRQ™ scores and specific outcomes (e.g., HCP actions taken/accessed, referrals to specialists, initiation of biologics) will be explored. Change in AIRQ™ score between the initial visit and follow-up visit(s) (using the AIRQ™ 3-Month Recall) will be explored when available by site and cluster.

Qualitative interviews will be summarized based on interviewers' notes and transcriptions. Audio-recordings of interviews from clinical site personnel will be referred to as necessary to supplement interviewer notes. The interview results will be summarized in tabular format, with key advantages, and disadvantages grouped. Additionally, findings from the implementation questions discussed during the clinical site touchpoint meetings will be integrated into the findings from the interviews. Facilitators, challenges and barriers, ease of implementation, and areas for improvement will be summarized. CCI

CCI

CCI

All analyses will be detailed in a Statistical Analysis Plan. Additional exploratory analyses may be performed to further examine specific aspects of available clinical data.

AMENDMENT HISTORY

Date	Section of study protocol	Amendment or update	Reason
June 16 2022		1	Revision of exploratory outcome 6 and removal of exploratory outcome 7. Update of site sample size maximum limit

MILESTONES

Milestone	Planned end date
Final Protocol	Q1 2021
IRB Study Protocol Approval	Q1 2021
Site Trainings	June 18, 2021
First Site In	February 15, 2021
First Subject In	March 15, 2021
Last Site in	June 15, 2021
Interviews with Site Principal Investigators/Key Staff	Mar 15, 2022
Database Lock	Q2 2022
High-Level Results in Tabular Format	Q3 2022
Final Report	September 26, 2022

1. BACKGROUND AND RATIONALE

1.1 Background

Uncontrolled and severe uncontrolled asthma (SUA) are under-identified and sub-optimally treated. The clinical and economic burden of SUA is disproportionately high, accounting for nearly 40% of asthma-related costs (Moore et al. 2007; Nunes et al. 2017); uncontrolled asthma affects more than 50% of children and adults with asthma. With advances in asthma therapies, an urgent need exists to optimize uncontrolled and SUA recognition and primary care management; and when indicated, referral to qualified specialists.

The AstraZeneca United States (US) PRECISION initiative formed an advisor network of scientific and clinical experts, as well as healthcare practitioners (HCPs), to develop a point-of-care tool—the Asthma Impairment and Risk Questionnaire™ (AIRQ™). This is designed to identify patients living with asthma whose health may be at risk from uncontrolled asthma, and to facilitate shared decision-making between patients and HCPs. The AIRQ™ is intended to be completed by patients before or at their HCP telehealth, or during an in-person clinic visit and includes questions that address medication use, asthma symptoms, exacerbations, hospitalizations, and asthma-related impairment. The final AIRQ™ consists of 10 yes/no items, with the total score and control categories used to identify patients at risk for poor asthma outcomes. All response options are in an easy yes/no format. In addition to the AIRQ™, HCPs are provided with the Asthma Checklist and supplemental educational resources, based on the Global Initiative for Asthma (GINA) guidelines, National Asthma Education and Prevention Program Guidelines (2007; 2020), and key expert reviews on asthma assessment and management to facilitate decision-making and developed by PRECISION Advisors and approved by the AstraZeneca Medical Information and Promotional Regulatory Affairs teams.

The AIRQ™, Asthma Checklist, and educational resources are for use among patients ≥12 years old with an asthma diagnosis and are designed for all HCPs to use following provider experience and comfort level. These resources are meant to assist providers in recognizing, evaluating, and optimizing care for patients with uncontrolled or SUA. They are not intended to be treatment directive or diagnostic, but rather to support HCPs in moving toward precision medicine in practice.

1.2 Rationale

To date, the AIRQ™ has been qualitatively evaluated among patients in an interview setting to ensure that it is understandable and easy to complete. The feasibility of implementing the AIRQ™ into a variety of clinical practices (i.e., allergy, pulmonary, and primary care) was evaluated in a pilot program that was well-received by patients and demonstrated the ease of

use by clinical staff. A cross-sectional validation study was conducted to validate the AIRQ™ relative to a composite of the Asthma Control Test™ (ACT™) score, plus medical-record documented prior-year exacerbations to derive the final AIRQ™ items, scoring, and cut points of varying levels of asthma control (Murphy et al. 2020). The final AIRQ™ consists of 10 yes/no items, with the total score and control categories used to identify patients at risk for poor asthma outcomes.

The AIRQ™ performs well in identifying patients who are well controlled vs. not well/very poorly controlled (with receiver operating characteristic [ROC] curves of 0.93 for the 0 to 10 summed score model) and identifies well/not well controlled vs. very poorly controlled asthma (ROC curves of 0.90 for the 0 to 10 summed score model), as reflected by the combined ACT™ score and prior-year exacerbations. The sensitivity of the AIRQ™ is 0.90 for separating well-controlled vs. all others, with a specificity of 0.96 for separating very poorly controlled from all others. A longitudinal study is being conducted to assess the predictive ability of the AIRQ™ as a screening tool for predicting future exacerbations as well as health-related quality of life (HRQoL).

This study aims to evaluate the implementation of the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) into clinical practice using telehealth and in-person platforms.

2. OBJECTIVES AND HYPOTHESES

2.1 Primary Objective & Hypothesis

The primary objective of this study is to assess the process (ease of use and challenges to HCPs and patients) and potential benefits (ability to capture and take action to remediate previously unrecognized morbidity) of implementing the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) into clinal practice during telehealth and in-person visits.

This study is descriptive and there will be no formal hypothesis testing for the primary objective.

2.2 Secondary Objectives

The secondary objectives of this study are:

1. To assess asthma patients' clinic visit experiences and when the AIRQ™, the Asthma Checklist, and educational resources (PRECISION program) are utilized as part of a telehealth or in-person visit with their HCP;

2. To explore change in AIRQ™ scores from the initial visit to follow-up visit(s) (when available).

2.3 Exploratory Objectives

The following are exploratory objectives:

CCI

CCI

CCI

CCI

CCI

CCI

3. METHODOLOGY

3.1 Study Design – General Aspects

The purpose of this community program intervention study is to examine the process of integrating the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) into clinical practice using either in-person or telehealth visits. Patients' responses to the AIRQ™, as well as the use of the Asthma Checklist and educational resources to guide treatment and asthma work-up and management, will be assessed. The duration of enrollment is nine months for each site (implementation stage), with an additional 3 months of follow-up to assess the sustainability of using the PRECISION program in clinical practice. The nine-month implementation stage allows for the recruitment of approximately 50 patients per site for an initial visit, plus the potential for follow-up visits during the study. The three-month sustainability stage will allow for sites to continue to implement the PRECISION program in their clinical practice and for sites to describe any continued benefits of implementing the PRECISION program at their site.

Approximately fifteen (15) to twenty (20) clinical sites will be recruited to participate in this study, categorized into the following four practice clusters: (1) primary care site (e.g., private practice, FQHC; (2) specialty care site (pulmonary, asthma/immunology); and (3) novel sites (e.g., pharmacy, nurse practitioners, nurse educators, prescribers and non-prescribers, telehealth component of Allergy and Asthma Network, pharmacy). While all sites will be able to conduct both in-person and telehealth visits, sites will aim to conduct approximately 25% of their initial patient visit using a telehealth platform (at a minimum). Both platforms (in-person and telehealth) can be used for the follow-up visit(s) for all clusters. Each site will recruit a target of approximately 50 patients per site, with a total sample size of approximately 750 to 1,500 patients. All patient completed materials will be available in English and Spanish.

Additionally, Evidera will host a 30-minute conference call with each clinical site for up to four (4) time points (touchpoints) to discuss the implementation of PRECISION tools (i.e., frequency of visits to and the number of PDF views from study website), assess whether sites are meeting their targets for using the telehealth platform, address site questions, and discuss any challenges of implementing the PRECISION program. These meetings will take place at Months 1, 2, 3 (optional), and 6 and will also be used to identify any sites that may benefit from participating in a re-training session. The optional Month 3 touchpoint will be based on whether the site is having any difficulties with the study. After the 9-month implementation stage is complete, each site will be followed for another 3 months (maintenance stage).

After verbally consenting patients (or parent/guardian when applicable) and documenting consent in the Patient Verbal Informed Consent Script, a staff member at the participating

clinical sites will administer the AIRQ™ to patients ≥13 years old with an HCP-confirmed asthma diagnosis who are presenting to the clinic (via telehealth or in-person). After completing the AIRQ™, patients will be asked if they would be willing to complete an additional survey, sent as an electronic link via email, following the initial visit. For those participants who agree, clinical staff will enter the patient's email address into a YouGov database so that an electronic survey link from YouGov will be emailed to the patient within 48 hours after the initial visit. This survey includes the following questionnaires: CCI CCI [redacted], the ACE Questionnaire, [redacted], and the Patient Sociodemographics Questionnaire. Up to two (2) reminder e-mails will be sent to participants who have yet to complete the survey within approximately one week (7 days) of receiving the initial survey link e-mail.

During the clinic visit (telehealth or in-person), HCPs will assess the patients' responses to the AIRQ™ questions and discuss the results with the patient, use the full Asthma Checklist (as appropriate per HCP judgment), and access the educational resources (PRECISION program) either at the point of care or after the visit to guide assessments, adjustments, and follow-up for reviewing responses to patient education and management interventions. If a follow-up visit is conducted, the clinical site will administer the AIRQ™ 3-month recall version. Sites/HCPs will complete a Clinical Case Report Form (CRF) after the initial visit and after the follow-up visit (if conducted) for each participant. It should be noted that for all visits (initial and baseline), HCPs will be required to review the Assess component of the Asthma Checklist and provide their responses on the CRF; the Adjust and Review components of the Asthma Checklist will be available on the study website as well, but will not be mandatory to complete, CCI [redacted]

The study team originally planned to collect exacerbation data to compare 12 months pre-initial visit to 12 months post-initial visit among patients from third-party payer sites. However, these sites were unable to participate in the study. Therefore, high performing sites were selected to recontact their participants to ask if they would be willing to participate in a chart review to be conducted 12 months after their initial study visit. If patients agree, sites will use a new verbal consent script specific for the 12-month post-initial visit exacerbation data. For patients who consent, the site will complete a 12-month post-initial visit exacerbation CRF form. Data will only be collected for patients who provide their verbal consent. Verbal consent will be documented on the 12-month post-initial visit exacerbation CRF form.

Evidera will host a 30-minute conference call with each clinical site for up to four-time points (touchpoints) to discuss the use of PRECISION tools, assess the mix of telehealth and in-person visits, address site questions, and discuss a set of questions that focus on the challenges and efficiencies of using the PRECISION program. These meetings will take place at Months

1, 2, 3 (optional), and 6 and will also be used to identify any sites that may benefit from participating in a re-training session. The optional Month 3 touchpoint will be based on whether the site is having any difficulties with the study. After the 9-month implementation stage is complete, each site will be followed for another three months (maintenance stage).

After patient enrollment and follow-up visits have been completed, prescribing providers at clinical sites (or the asthma coaches from the novel cluster of the Asthma and Allergy Network, or Non-prescribers, or nurse case-managers) will self-complete the Post-study Survey. The focus of this questionnaire will be to obtain feedback on the implementation of the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) as part of their clinical practice (telehealth platform and in-person).

Finally, the principal investigator from each site and key site staff (up to three staff members per site) will participate in a qualitative interview to gain a full understanding of the processes and issues related to implementing the AIRQ™, Asthma Checklist and educational resources (PRECISION program) as part of their clinical practice (telehealth and in-person visits). Additionally, the interviews will explore the best practices that may have been unique to their site, as well as plans for continuing the use of the AIRQ™ and PRECISION tools. The telephone interviews will be conducted approximately 9 to12 months from study implementation for each site and will last up to 60 minutes; all interviews will be audio-recorded and transcribed.

3.1.1 Data Source(s)

Approximately fifteen (15) to twenty (20) clinical sites will be selected to implement the AIRQ™, the Asthma Checklist, and educational resources (PRECISION program) into clinical practice using telehealth and in-person platforms. The sites will be selected based on the site principal investigator's experience and qualifications, use of a telehealth platform as part of their care practice, the number of asthma patients visiting the clinic via telehealth per week, the diversity of the asthma patients treated by the clinic, the ability of the site to complete the study tasks in the allotted timeframe, and the anticipated unique component(s) used to contribute to the implementation process by the study site. Each site will be responsible for recruiting approximately 50 asthma patients per site.

3.2 Study Population

Clinic staff will invite patients ≥13 years old with an HCP-confirmed asthma diagnosis who are presenting for a telehealth or in-person visit to complete the AIRQ™. Each site will aim to recruit approximately 50 patients, with a total sample size of 750 to 1,500 patients.

3.3 Inclusion Criteria

Patients must meet all of the following criteria to be eligible for enrollment:

1. ≥ 13 years of age at the time of enrollment
2. Diagnosis of HCP-confirmed asthma
3. Able to read, understand and speak English or Spanish sufficiently self-complete or be administered the AIRQ™ via telephone, desktop, or mobile device (e.g., smartphone, iPad)
4. Provide consent (adults/parents/guardians) and assent (age 13-17 years) to participate in the study.

3.4 Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Current diagnosis of active COPD or any lower respiratory diagnosis other than asthma
2. Has a cognitive impairment, hearing difficulty, acute psychopathology, medical condition, or insufficient knowledge of the English or Spanish language that, in the opinion of the investigator, would interfere with his or her ability to agree to participate and/or complete the AIRQ™ or other study questionnaires

4. VARIABLES AND EPIDEMIOLOGICAL MEASUREMENTS

4.1 Exposures

4.1.1 Patient Verbal Informed Consent Scripts

Verbal Informed Consent scripts for participants ≥18 years old, available in English and Spanish (Appendix A and Appendix B) and Verbal Informed Consent/Assent scripts for participants <18 years old, available in English and Spanish (Appendix C and Appendix D) will be used to introduce the study before the patient's visit (during the appointment reminder call) or during the visit (telehealth platform; in-person) to provide more information about the study and to document verbal consent and verbal assent in minors.

4.1.2 AIRQ™

The AIRQ™ (Appendix E) consists of 10 yes/no items, with the total score used to identify patients at risk for poor asthma outcomes. The AIRQ™ questions address medication use, asthma symptoms, exacerbations, unscheduled medical telehealth visits, hospitalizations, and asthma-related impairment. The majority of AIRQ™ items use a two-week recall period (questions 1 through 7), while the risk items use a recall period of the prior 12 months. The AIRQ™ is available in English and Spanish (Appendix F); both versions will be used in this

study. The AIRQ™ is also available in a 3-month recall version in English (Appendix G) and Spanish (Appendix H).

Sites will be asked to ensure that the AIRQ^{TM} is completed before the patient sees the HCP. For in-person visits, the AIRQ^{TM} can be completed by the patients on paper (self-administration) or completed by site staff as interviewer-administered. For telehealth visits, the AIRQ^{TM} can be sent to patients in advance of the visit (e.g., sent via email as a PDF or sent via a link to www.digitalairq.com) and completed by the patients on paper (self-administration) or completed by site staff as interviewer-administered. In the case that the patient receives the AIRQ^{TM} in advance of their visit, the patient can provide their responses on the self-completed AIRQ^{TM} to the site staff who will then transpose patient responses to the CRF paper version of the AIRQ^{TM} and provide to the HCP at the start of the visit. Examples of ways to administer the AIRQ^{TM} during a telehealth visit will be provided as part of the site training.

4.1.3 Clinical Case Report Form

For each participant, the clinical site will complete a Clinical CRF (Appendix I) during the initial site telehealth visit. The Clinical CRF serves to characterize patients based on their asthma history, current medications, time since most recent spirometry, the HCP's rating of the patient's asthma severity and control, 12-month history of chart-reported exacerbations (when available), Assess component of the Asthma Checklist, and a treatment plan based on AIRQ™ score at the baseline telehealth visit (step-up/step down/no change).

4.1.4 Follow-up Clinical Clinical Case Report Form (CRF)

A FOLLOW-UP CLINICAL CRF WILL BE COMPLETED FOR THOSE PATIENTS WITH A FOLLOW-UP VISIT (TELEHEALTH/IN-PERSON) DURING THE FOLLOW-UP PERIOD WHICH WILL DOCUMENT THE HCP'S RATING OF THE PATIENT'S ASTHMA SEVERITY AND CONTROL, CHART-REPORTED EXACERBATIONS (WHEN AVAILABLE), ASSESS COMPONENT OF THE ASTHMA CHECKLIST, AND A TREATMENT PLAN BASED ON AIRQ™ 3-MONTH RECALL SCORE AT FOLLOW-UP VISIT (E.G., STEP-UP/STEP DOWN/NO CHANGE, REFERRAL) (

Evidera # 138 Plate # 005 Visit # 001

Participant ID

13. Other health conditions (Please mark all boxes that apply with an "X.")

- ☐ **No other health conditions**
- ☐ Allergy diagnosed by blood or skin testing
- ☐ Allergic rhinitis (nasal allergies, "hay fever")
- ☐ Aeroallergens
- ☐ Heart disease (history of heart attack, heart failure, or heart valve problems)
- ☐ Anxiety
- ☐ Anaphylaxis (severe allergic reaction to a food, bee sting, allergy shot, medication, or other)
- ☐ Arthritis
- ☐ Aspirin sensitivity (aspirin causes hives, swelling, or breathing problems)
- ☐ Atopic dermatitis/Eczema
- ☐ Chronic bronchitis
- ☐ Chronic Obstructive Pulmonary Disease (COPD)
- ☐ Chronic sinusitis
- ☐ Depression
- ☐ Diabetes
- ☐ Emphysema
- ☐ GERD (heartburn/reflux)
- ☐ Hypertension (high blood pressure)
- ☐ Nasal Polyps
- ☐ Sleep Apnea
- ☐ Stroke
- ☐ Other (specify): _____
- ☐ **Unknown**

14. Was spirometry lung function testing performed on this patient in the last 12 months?

☐ Yes (Record below): Date of most recent spirometry ☐☐ (DD) ☐☐☐ (MMM) 20☐☐ (YYYY)

☐ No

Pre-bronchodilator

FVC: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1/FVC ratio 0.☐☐

☐ Not Available

Post-bronchodilator

FVC: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1/FVC ratio 0.☐☐

☐ Not Available

Evidera # 138 Plate # 006 Visit # 001

Participant ID ☐☐☐ ☐☐☐

15. Please indicate asthma exacerbation history within the prior 12 months:

ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

15.1 Number of times in the past 12 months asthma symptoms **required an emergency department or urgent care visit (but not an overnight stay in the hospital):**

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

15.2 Number of times in the past 12 months that there was a worsening in asthma symptoms that **required a hospital stay for greater than 24 hours**:

☐☐ times admitted to hospital ☐ None

15.3 Number of unplanned ambulatory clinic visits due to exacerbation in past 12 months:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐
f. ☐☐ ☐☐☐ ☐☐☐☐

15.4 How many courses of oral corticosteroids (OCS) was the patient prescribed over the past 12 months for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma within 12 months
☐ 1 OCS course only for asthma within the past 12 months
☐ 2 OCS courses only for asthma within the past 12 months
☐ 3 OCS courses for asthma within the past 12 months
☐ ≥ 4 OCS courses for asthma within the past 12 months
☐ patient is on daily OCS

15.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Evidera # 138 Plate # 007 Visit # 001

Participant ID

☐☐☐ ☐☐☐

16. Following the use of the PRECISION program, which of the following will you do to the patient's medication after today's telehealth visit? (check all that apply)

- ☐ Step-down of controller medicines
- ☐ No change to the level of controller therapy
- ☐ Step-up of controller medicines
- ☐ Prescribe a course of systemic corticosteroids
- ☐ Begin work-up for possible biologic
- ☐ Begin biologic: (specify): _____
- ☐ Other: (specify): _____

Part 4. Asthma Checklist (Assess content only)

1. Please check the Asthma Checklist Assess items (page 1) that were considered during the visit:

CONSIDER FOR ALL PATIENTS REGARDLESS OF ASTHMA CONTROL

- ☐ Adherence[1-3]
- ☐ Appropriate Therapy[1,3]
- ☐ Asthma Action Plan[1,2,4]
- ☐ Inhaler Technique[1,2,4]
- ☐ Psychological Issues[1,2]
- ☐ Spirometry[1,2,4]
- ☐ Tobacco Use[1,2,5]
- ☐ Vaccinations[1,2,6,7]

CONSIDER FOR PATIENTS WITH UNCONTROLLED SYMPTOMS AND/OR RISK FACTORS FOR EXACERBATIONS

- ☐ Asthma Phenotyping[1-4]
- ☐ Comorbidities[1,2]
- ☐ Home and/or Work Exposures[1,2,4]
- ☐ Referral to an Asthma Specialty Center, or Other Appropriate Specialist or Health Care Provider in Your Area[1,2]
- ☐ Alternative Diagnoses and Hidden Comorbidities[1,2]
- ☐ Optimizing Therapy with Add-on or Advanced Treatment[1,3]

Investigator/Coordinator Signature: _____

Date: ☐☐ DD ☐☐☐ MMM 2☐☐☐ YYYY

Appendix J).

4.1.5 12-Month Post-Initial Visit Exacerbation Clinical Case Report Form (CRF)

For each consented participant from the sites selected for the pre/post exacerbation data comparison, the site will complete a follow-up clinical case report form that includes chart-reported exacerbations 12-months after the initial study visit (Appendix J).

4.1.6 Study Website

Sites will have access to the study website PPD which includes the Asthma Checklist and PRECISION Educational Resources (

12-Month Post-Initial Visit Exacerbation Clinical Case Report Form

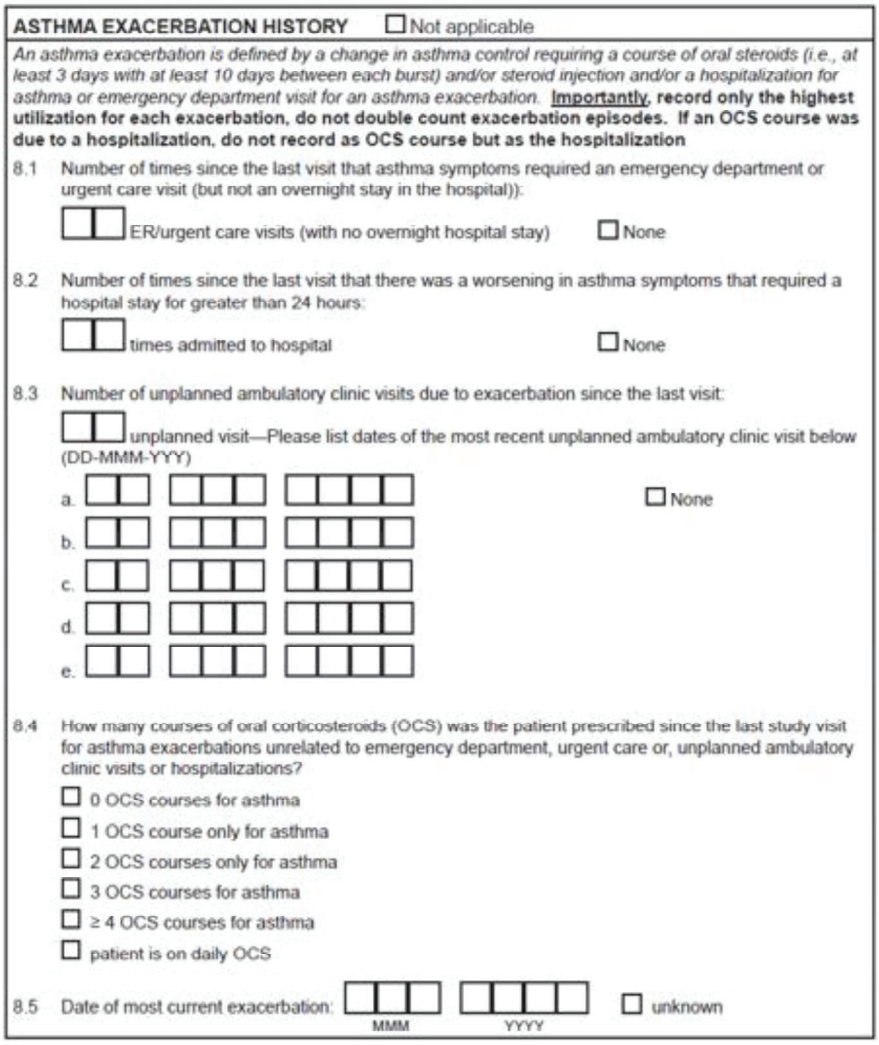
Participant ID: ___ - ____

Verbal Consent Provided: ☐ Yes ☐ No

Date verbal consent provided: MM/DD/YYYY

Date form completed: MM/DD/YYYY

Please indicate the asthma exacerbation history since the patients initial study visit (12 months ago):



ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

8.1 Number of times since the last visit that asthma symptoms required an emergency department or urgent care visit (but not an overnight stay in the hospital)):

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

8.2 Number of times since the last visit that there was a worsening in asthma symptoms that required a hospital stay for greater than 24 hours:

☐☐ times admitted to hospital ☐ None

8.3 Number of unplanned ambulatory clinic visits due to exacerbation since the last visit:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐

8.4 How many courses of oral corticosteroids (OCS) was the patient prescribed since the last study visit for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma
☐ 1 OCS course only for asthma
☐ 2 OCS courses only for asthma
☐ 3 OCS courses for asthma
☐ ≥ 4 OCS courses for asthma
☐ patient is on daily OCS

8.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Investigator/Coordinator Signature: _____

Appendix K).

4.1.7 Asthma Checklist

The Asthma Checklist (see provider-facing tools in

12-Month Post-Initial Visit Exacerbation Clinical Case Report Form

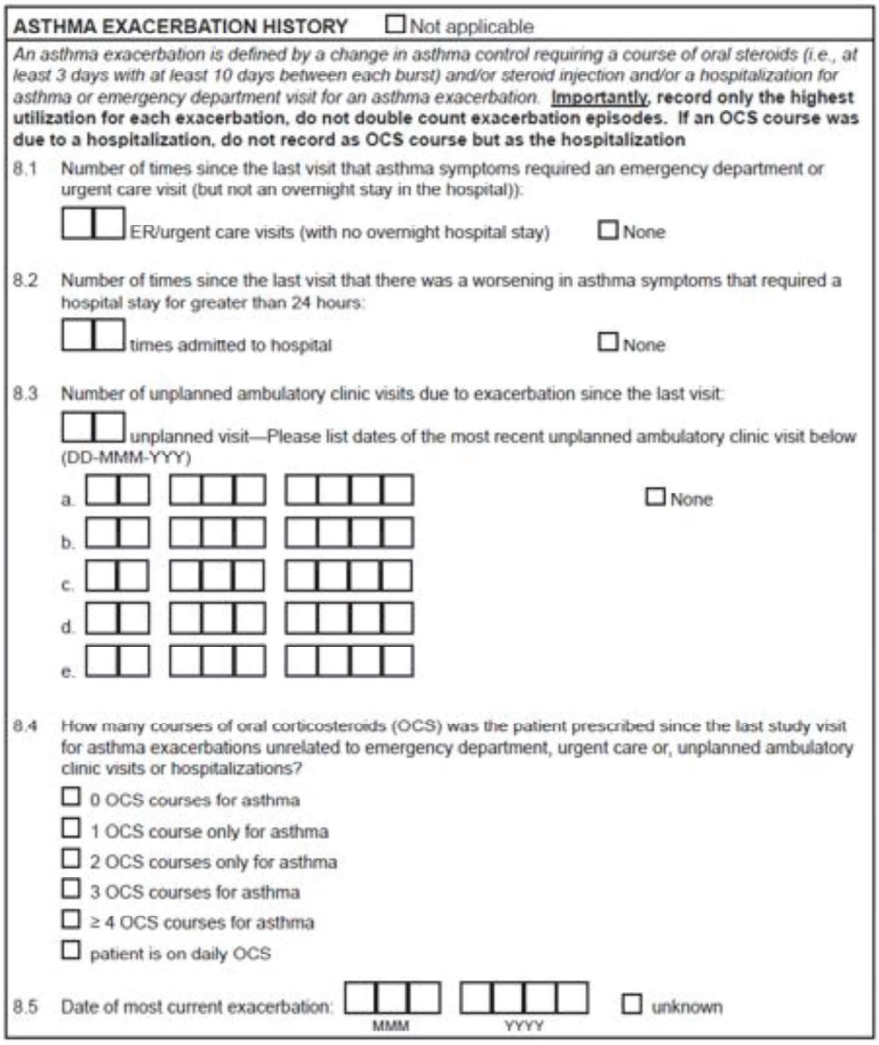
Participant ID: ___ - ____

Verbal Consent Provided: ☐ Yes ☐ No

Date verbal consent provided: MM/DD/YYYY

Date form completed: MM/DD/YYYY

Please indicate the asthma exacerbation history since the patients initial study visit (12 months ago):



ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

8.1 Number of times since the last visit that asthma symptoms required an emergency department or urgent care visit (but not an overnight stay in the hospital)):

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

8.2 Number of times since the last visit that there was a worsening in asthma symptoms that required a hospital stay for greater than 24 hours:

☐☐ times admitted to hospital ☐ None

8.3 Number of unplanned ambulatory clinic visits due to exacerbation since the last visit:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐

8.4 How many courses of oral corticosteroids (OCS) was the patient prescribed since the last study visit for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma
☐ 1 OCS course only for asthma
☐ 2 OCS courses only for asthma
☐ 3 OCS courses for asthma
☐ ≥ 4 OCS courses for asthma
☐ patient is on daily OCS

8.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Investigator/Coordinator Signature: _____

APPENDIX K) IS BASED ON GINA AND THE NATIONAL ASTHMA EDUCATION AND PREVENTION PROGRAM (NAEPP) GUIDELINES. THIS THREE-PAGE TOOL IS DESIGNED TO ASSIST PROVIDERS WITH RECOGNITION, EVALUATION, AND OPTIMIZATION OF ALL PATIENTS WITH ASTHMA, THOSE WHO MAY BE UNCONTROLLED, AND THOSE WITH SEVERE ASTHMA (UNTREATED, DIFFICULT TO TREAT, REFRACTORY). PROVIDERS WILL BE ASKED TO COMPLETE THE ASSESS COMPONENT OF THE ASTHMA CHECKLIST AS PART OF THE CLINICAL CRF

(APPENDIX I) FOR ALL BASELINE STUDY VISITS AND AS PART OF THE FOLLOW-UP CLINICAL CRF (

Evidera # 138 Plate # 005 Visit # 001

Participant ID

13. Other health conditions (Please mark all boxes that apply with an "X.")

- ☐ **No other health conditions**
- ☐ Allergy diagnosed by blood or skin testing
- ☐ Allergic rhinitis (nasal allergies, "hay fever")
- ☐ Aeroallergens
- ☐ Heart disease (history of heart attack, heart failure, or heart valve problems)
- ☐ Anxiety
- ☐ Anaphylaxis (severe allergic reaction to a food, bee sting, allergy shot, medication, or other)
- ☐ Arthritis
- ☐ Aspirin sensitivity (aspirin causes hives, swelling, or breathing problems)
- ☐ Atopic dermatitis/Eczema
- ☐ Chronic bronchitis
- ☐ Chronic Obstructive Pulmonary Disease (COPD)
- ☐ Chronic sinusitis
- ☐ Depression
- ☐ Diabetes
- ☐ Emphysema
- ☐ GERD (heartburn/reflux)
- ☐ Hypertension (high blood pressure)
- ☐ Nasal Polyps
- ☐ Sleep Apnea
- ☐ Stroke
- ☐ Other (specify): _____
- ☐ **Unknown**

14. Was spirometry lung function testing performed on this patient in the last 12 months?

☐ Yes (Record below): Date of most recent spirometry ☐☐ (DD) ☐☐☐ (MMM) 20☐☐ (YYYY)

☐ No

Pre-bronchodilator

FVC: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1/FVC ratio 0.☐☐

☐ Not Available

Post-bronchodilator

FVC: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1: ☐.☐☐☐ L

☐☐☐ % (predicted)

FEV1/FVC ratio 0.☐☐

☐ Not Available

Evidera # 138 Plate # 006 Visit # 001

Participant ID ☐☐☐ ☐☐☐

15. Please indicate asthma exacerbation history within the prior 12 months:

ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

15.1 Number of times in the past 12 months asthma symptoms **required an emergency department or urgent care visit (but not an overnight stay in the hospital):**

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

15.2 Number of times in the past 12 months that there was a worsening in asthma symptoms that **required a hospital stay for greater than 24 hours**:

☐☐ times admitted to hospital ☐ None

15.3 Number of unplanned ambulatory clinic visits due to exacerbation in past 12 months:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐
f. ☐☐ ☐☐☐ ☐☐☐☐

15.4 How many courses of oral corticosteroids (OCS) was the patient prescribed over the past 12 months for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma within 12 months
☐ 1 OCS course only for asthma within the past 12 months
☐ 2 OCS courses only for asthma within the past 12 months
☐ 3 OCS courses for asthma within the past 12 months
☐ ≥ 4 OCS courses for asthma within the past 12 months
☐ patient is on daily OCS

15.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Evidera # 138 Plate # 007 Visit # 001

Participant ID

☐☐☐ ☐☐☐

16. Following the use of the PRECISION program, which of the following will you do to the patient's medication after today's telehealth visit? (check all that apply)

- ☐ Step-down of controller medicines
- ☐ No change to the level of controller therapy
- ☐ Step-up of controller medicines
- ☐ Prescribe a course of systemic corticosteroids
- ☐ Begin work-up for possible biologic
- ☐ Begin biologic: (specify): _____
- ☐ Other: (specify): _____

Part 4. Asthma Checklist (Assess content only)

1. Please check the Asthma Checklist Assess items (page 1) that were considered during the visit:

CONSIDER FOR ALL PATIENTS REGARDLESS OF ASTHMA CONTROL

- ☐ Adherence[1-3]
- ☐ Appropriate Therapy[1,3]
- ☐ Asthma Action Plan[1,2,4]
- ☐ Inhaler Technique[1,2,4]
- ☐ Psychological Issues[1,2]
- ☐ Spirometry[1,2,4]
- ☐ Tobacco Use[1,2,5]
- ☐ Vaccinations[1,2,6,7]

CONSIDER FOR PATIENTS WITH UNCONTROLLED SYMPTOMS AND/OR RISK FACTORS FOR EXACERBATIONS

- ☐ Asthma Phenotyping[1-4]
- ☐ Comorbidities[1,2]
- ☐ Home and/or Work Exposures[1,2,4]
- ☐ Referral to an Asthma Specialty Center, or Other Appropriate Specialist or Health Care Provider in Your Area[1,2]
- ☐ Alternative Diagnoses and Hidden Comorbidities[1,2]
- ☐ Optimizing Therapy with Add-on or Advanced Treatment[1,3]

Investigator/Coordinator Signature: _____

Date: ☐☐ DD ☐☐☐ MMM 2☐☐☐ YYYY

Appendix J) to support the assessment of their patient, but to the degree, they feel is most appropriate for the particular patient and particular circumstances of the visit. The Adjust and Review Responses component of the Asthma Checklist (pages 2 and 3) will be recommended for review by HCP but remain optional.

4.1.8 PRECISION Educational Resources

Providers will have access to the study webpage which will contain the provider-facing materials and the patient-facing education resources included in the PRECISION program (

12-Month Post-Initial Visit Exacerbation Clinical Case Report Form

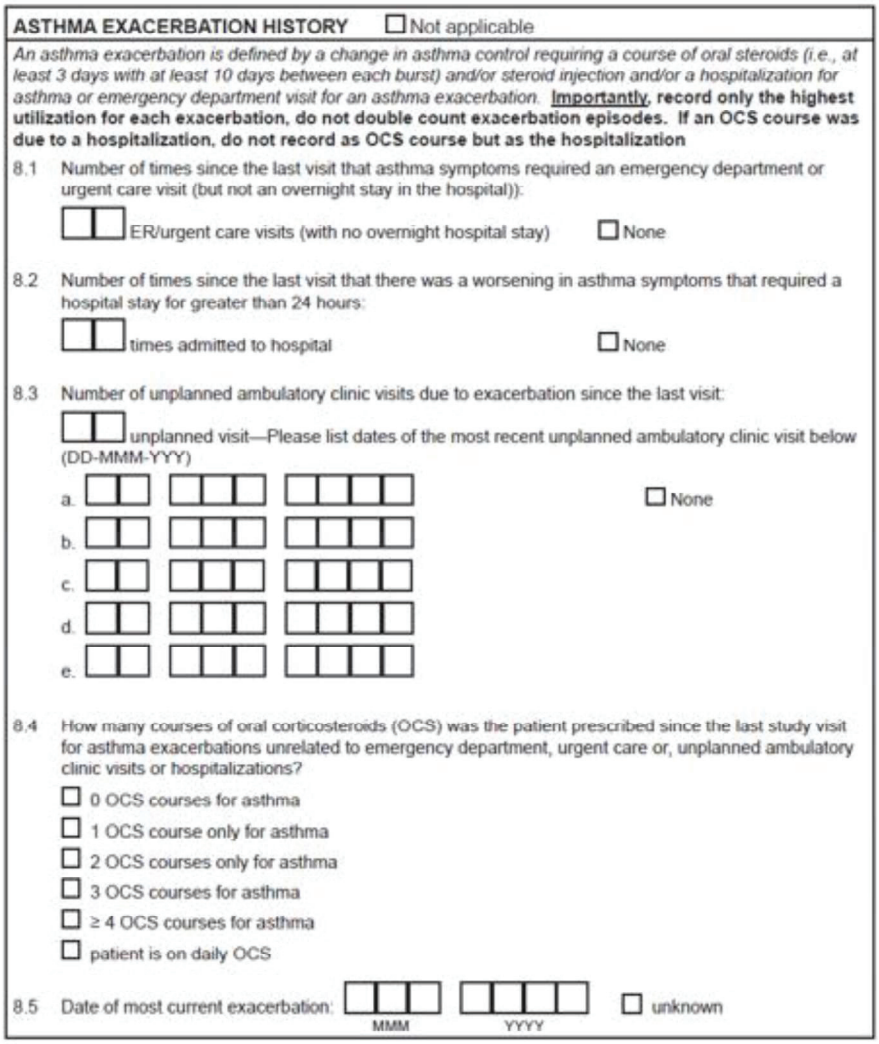
Participant ID: ___ - ____

Verbal Consent Provided: ☐ Yes ☐ No

Date verbal consent provided: MM/DD/YYYY

Date form completed: MM/DD/YYYY

Please indicate the asthma exacerbation history since the patients initial study visit (12 months ago):



ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

8.1 Number of times since the last visit that asthma symptoms required an emergency department or urgent care visit (but not an overnight stay in the hospital)):

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

8.2 Number of times since the last visit that there was a worsening in asthma symptoms that required a hospital stay for greater than 24 hours:

☐☐ times admitted to hospital ☐ None

8.3 Number of unplanned ambulatory clinic visits due to exacerbation since the last visit:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐

8.4 How many courses of oral corticosteroids (OCS) was the patient prescribed since the last study visit for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma
☐ 1 OCS course only for asthma
☐ 2 OCS courses only for asthma
☐ 3 OCS courses for asthma
☐ ≥ 4 OCS courses for asthma
☐ patient is on daily OCS

8.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Investigator/Coordinator Signature: _____

Appendix K). All resources can be accessed as desired either during patient visits or as resources before/after visits. Resources may be downloaded as desired and used during patient visits and patient-facing materials can also be sent electronically to patients per the discretion of the HCP.

4.1.9 Asthma Clinic Experience (ACE) Questionnaire

The ACE Questionnaire (Appendix L) is a self-administered electronic questionnaire that includes nine questions using a four-point Likert scale (strongly agree, agree, disagree, strongly disagree). Patients who agree will be sent this questionnaire via an e-mailed survey link following their initial visit. Patients are asked to think about how completing the AIRQ™

as part of their telehealth visit may have affected their experience when answering the questions. The ACE Questionnaire will be available in English and Spanish (Appendix M).

4.1.12 Patient Sociodemographics Questionnaire

Sites will collect basic participant demographic information on the Clinical CRF—age, gender, and race. Participants who agree will be asked to complete additional demographic questions (Appendix R). This form collects the participant's ethnicity, living situation, employment, and education, and will be used to describe the sample and assist with interpreting the results. Patients will be sent this questionnaire via an e-mailed web-link following their initial visit. The Patient Demographic Questionnaire will be available in English and Spanish (Appendix S).

4.1.13 Clinical Site Touchpoint Questions

Evidera will conduct 30-minute conference calls with each clinical site for up to four (4) time points (touchpoints) to discuss the use of PRECISION tools, address site questions, and discuss a set of discussion questions that focus on the facilitators and barriers/challenges of implementing the PRECISION program (Appendix T). The same touchpoint implementation

questions will be asked to all clinical staff participating in each scheduled meeting: Months 1, 2, 3 (optional), and 6.

4.1.14 Post-study Survey

All HCPs who participated in at least 10 telehealth or in-person visits will be invited to complete the Post-study Survey (paper form) (Appendix U). The purpose of this survey is to obtain feedback on the implementation of the AIRQ™ within each site's clinical practice (telehealth platform and in-person visit).

4.1.15 Semi-structured Interview Guide

A semi-structured interview guide (Appendix V) will be used by the interviewer to obtain information from the principal investigator and key clinical site staff (up to three interviews per site) to gain a deeper understanding of the feasibility of implementing the AIRQ™ via telehealth and in-person, as well as sustainability of using the PRECISION program in their clinical practice. The semi-structured interview guide will include an introduction and specific questions/probes designed to facilitate discussion and optimize consistency across interviews. The interview guide will elicit from site personnel the process for implementing the AIRQ™, and recommendations for improving processes related to telehealth and in-person implementation. Also, any specific initiatives that were integrated into various practices will be discussed. Additional unscripted probes may also be used to gain further information or clarification.

4.2 Outcomes

4.2.1 Primary Outcome

To address the primary objective of assessing the process and potential benefits when integrating the AIRQ™ PRECISION program on a telehealth or in-person platform, the following outcomes will be assessed:

- **Post-study Telehealth Survey**: Descriptive statistics (n, frequency, mean, and standard deviation [SD]) will be used to summarize the results from the Post-study Survey.
- **Qualitative Interviews**: Results from the qualitative interviews will be summarized in tabular format, with key recommendations, advantages, and disadvantages grouped. Specifically, barriers, benefits, challenges, ease of implementation, and areas for improvement will be summarized. Also, the summary will capture if the PRECISION program has been utilized in clinical practice post-implementation, or what would need to be done to support the continued use of the PRECISION program in their clinical practice.
- **Implementation Touchpoint Discussion with Sites**: Key findings from the implementation questions discussed during the clinical site touchpoint meetings

(including barriers and subsequent ways in which these barriers were addressed) will be summarized.

4.2.2 Secondary Outcome

1. To address the secondary objective of assessing patient telehealth or in-person visit satisfaction when the AIRQ™ is initiated as part of a telehealth or in-person visit with their HCP, the following outcomes will be assessed:

    - ACE Questionnaire Responses: Descriptive statistics (n, frequency, mean, and SD) will be used to summarize by item for all nine items.

2. To explore change in AIRQ™ scores from initial visit to follow-up visits:

    - 12M AIRQ™ (initial study visit)
    - 3M AIRQ™ (follow-up visits)

4.2.3 Exploratory Outcomes

CCI [redacted]

CCI

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

CCI CCI [redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted] CCI [redacted]

CCI

CCI [redacted]

- [redacted]

4.3 Other Variables and Covariates

Additional variables and covariates may be examined based on the availability of data. A more detailed description of additional variables and covariates will be included in the Statistical Analysis Plan.

5. STATISTICAL ANALYSIS PLAN

5.1 Statistical Methods – General Aspects

Descriptive statistics (n, frequency, mean, SD, median, range) will be used to characterize the sample in terms of sociodemographic and clinical characteristics and to summarize qualitative outcomes. These characteristics will be summarized for the sample overall, as well as for each site and cluster.

Additional analyses, including various subgroup analyses, to aid in the interpretation of the defined outcome measures may also be conducted and will be described in the Statistical Analysis Plan.

5.1.1 Primary Objective(s): Assess the Process and Potential Benefit of Implementing the AIRQ™, Asthma Checklist, and Educational Resources (PRECISION program) into Clinical Practice during Telehealth and In-Person Visits

Descriptive statistics (n, frequency, mean, SD, and 95% confidence intervals [Cis]) will be used to assess the process and potential benefits when integrating the AIRQ™ on a telehealth and in-person platform. Qualitative interviews will be summarized based on the interviewers' notes and the transcribed interviews. Findings from the touchpoint discussions with sites will be integrated into the qualitative findings. Audio recordings of interviews from clinical site personnel will be referred to as necessary to supplement interviewer notes and transcriptions. The interview results will be summarized in tabular format, with key recommendations, advantages, and disadvantages grouped accordingly. Specifically, barriers, benefits, challenges, ease of implementation, and areas for improvement will be summarized. Lastly, the results from the Post-study Survey will be summarized using descriptive statistics.

5.1.2 Secondary Objective(s): To Assess Patient Visit Satisfaction When the AIRQ™ Is Initiated as Part of a Telehealth or In-Person visit with Their HCP

To assess patient satisfaction with the AIRQ™, descriptive statistics (n, frequency, mean, SD, and 95% CIs) will be used to summarize patients' responses to the ACE Questionnaire. Subgroup analysis may be conducted to examine responses by site, cluster, platform used, or AIRQ^{TM} score.

Change in AIRQ™ score and control level between the initial telehealth visit and follow-up visit(s) (using the AIRQ™ 3-Month Recall when available) will be explored by site and cluster and presented using descriptive statistics (n, frequency, mean, and SD) and mean change of AIRQ™ by item and total score, (95% CIs computed; initial visit vs. follow-up visits) and a shift analysis for control level.

Change in AIRQ™ score and control level between the initial telehealth visit AIRQ^{TM} (12-Month Recall) and follow-up visit(s) (using the AIRQ™ 3-Month Recall when available) will be stratified by site and cluster and presented using descriptive statistics (n, frequency, mean, and SD). Mean change of AIRQ™ by item and total score (95% CIs computed; initial visit vs. follow-up visits) and a shift analysis for control level will be conducted.

5.1.3 Exploratory Objective(s): CCI

CCI

CCI

CCI

CCI

CCI

CCI

All analyses will be detailed in a Statistical Analysis Plan. Additional exploratory analyses may be performed to further examine specific aspects of available clinical data.

5.2 Bias

5.2.1 Methods to Minimize Bias

Given that completing the ACE Questionnaire is optional, the potential for response bias (e.g., patients who like the telehealth platform may be more inclined to complete the survey) may be introduced into this study. This will be noted when interpreting the results. Additionally, patients who have a follow-up assessment may be more severe than those who do not; thus, change scores may not be representative of the entire sample, which will also be noted when interpreting results.

5.2.2 Adjustment for Multiple Comparisons

Not applicable.

5.2.3 Strengths and Limitations

The strengths of this study are that it aims to include a variety of clinical practice types, that the clinical sites have access to diverse patient populations, and the study will have a large sample size. The limitations of this study include that up to 20 clinical sites may not be generalizable to all clinical sites treating asthma patients across the US, and that the patient sample may not be generalizable to all asthma patients ≥13 years old across the US.

5.3 Sample Size and Power Calculations

As the aim of this study is to assess the process and feasibility of implementing the AIRQ™ using a telehealth platform, inferential statistics will not be conducted, and a formal sample size estimation is not applicable. Each site will target approximately 50 patients; however, some sites may be able to recruit more than 50 patients, resulting in a total sample size of approximately 750 to 1,500 patients. Further, each cluster (primary care, specialist, novel) will

contain approximately 3 to 5 sites to have balanced sample sizes between the practice clusters. Implementing the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) among approximately 50 patients will provide sites with enough experience to provide feedback on the outcomes, barriers, benefits, challenges, ease of implementation, and areas for improvement for future integration as a telehealth and in-person platform. Additionally, an adequate sample should be available to confirm the performance of the AIRQ™ in a diverse primary care cluster.

6. STUDY CONDUCT AND REGULATORY DETAILS

6.1 Study Conduct

6.1.1 Study Flow Chart and Plan for Telehealth or In-Person Visits

Figure 1. Study Flow Overview of Initial Telehealth or In-Person Visit

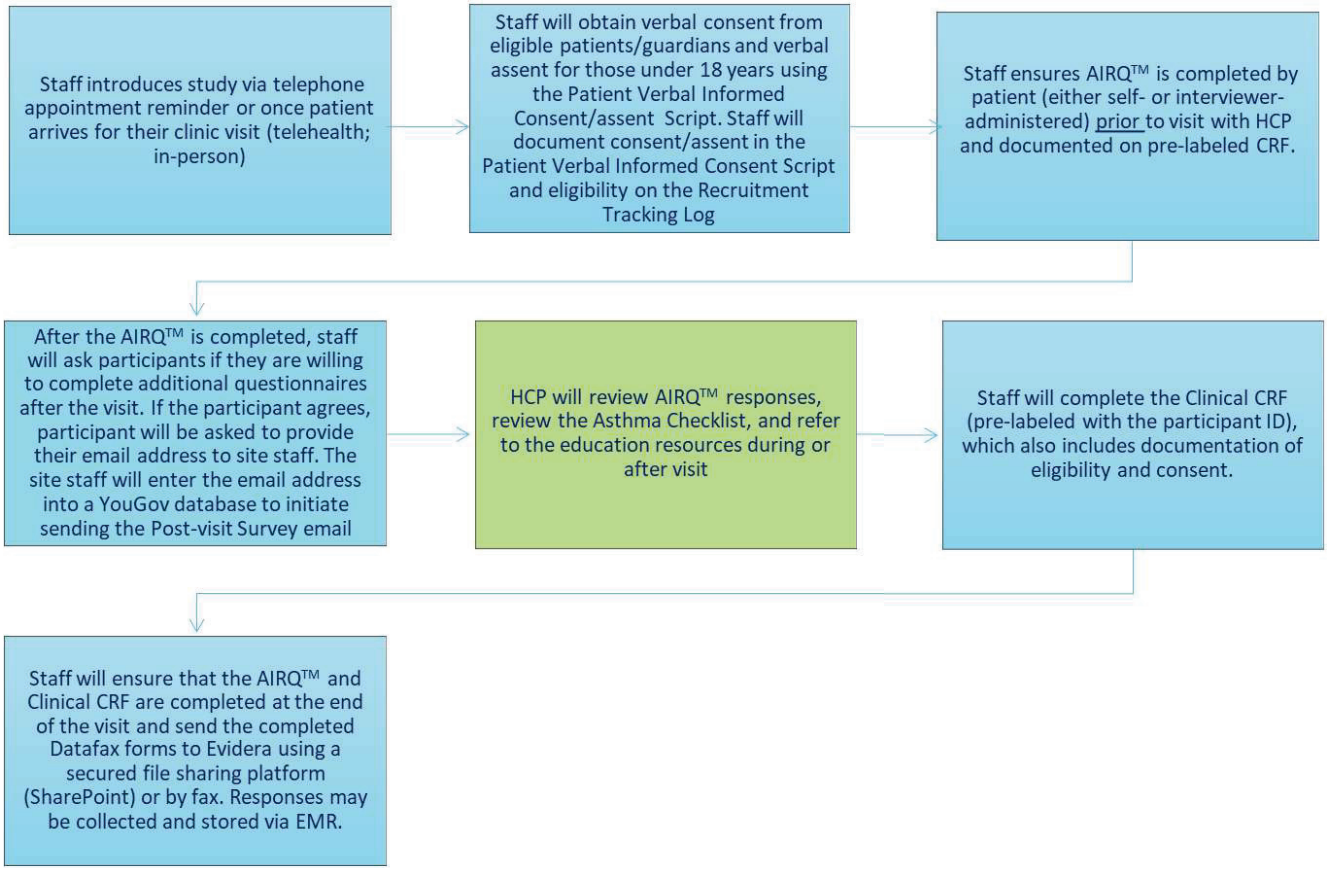


Figure 2. Overview of the Follow-up Telehealth or In-person Visit Study Flow

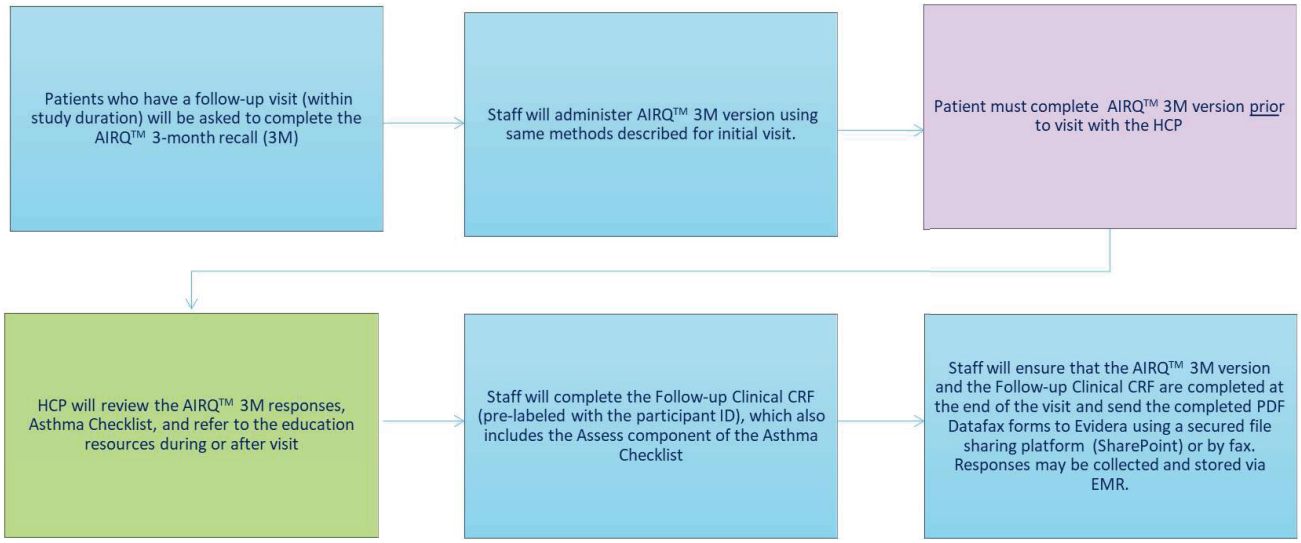


Table 1. Study Plan

Study Procedure	Timing	Completed by:	
		Clinical Site (Staff/HCP)	Patient
Telephone Introduction to Study	At time of appointment reminder (if not automated)	X	
Introduction to Study	At the initial visit (telehealth; in-person)	X	
Document Consent/Assent	At the initial visit (telehealth; in-person)	X	
Clinical CRF, which includes the Assess component of the Asthma Checklist (page 1)	At the initial visit (telehealth; in-person)	X	
AIRQ™	At the initial visit (telehealth; in-person)		X
ACE Questionnaire	Sent to patient within approx. 48 hours following initial visit via e-mail link (two email reminders)		X
CCI	[redacted]		X
CCI [redacted]			X

Study Procedure	Timing	Completed by:	
		Clinical Site (Staff/HCP)	Patient
Patient Sociodemographics Questionnaire	Sent to patient within approx. 48 hours following initial visit via e-mail link (two email reminders)		X
AIRQ™ 3-month Recall	Used at the follow-up visit (telehealth; in-person), should a follow-up visit occur		X
Follow up Clinical CRF, which includes the Assess component of the Asthma Checklist(page 1)	Used at the follow-up visit (telehealth; in-person), should a follow-up visit occur	X	
Clinical Site Touchpoint Questions	Up to 4 meetings over the 6-month patient recruitment period	X	
Post-study Survey	After patient enrollment is nearly completed (approximately 30 telehealth visits)	X	
Qualitative Interviews with Site Principal Investigator and Key Staff	After patient enrollment is completed	X	
12 Month Post-Initial Visit Exacerbation CRF	Used to collect 12-month post-initial visit exacerbation data for patients at selected sites who consented	X	

6.1.2 Procedures

Patients will be recruited from approximately 15 to 20 clinical sites in geographically diverse locations across the US. Clinical site staff will identify and verify the initial eligibility of potential participants through a review of patient records. Clinical sites may identify potential participants through daily telehealth visit schedules, chart/database/emergency medical record reviews, or recruit via advertisement (Asthma and Allergy Network only) (Appendix X). Clinical site staff and/or prescribing HCPs will ensure the completion (either self- or interviewer-administered) of the AIRQ™ and the AIRQ™ 3-month Recall when follow-up visits may occur during the study follow-up period of 6 months after enrollment, complete the assessment component of the Asthma Checklist, and implement educational resources (PRECISION program), as well as complete the Clinical CRF and the Follow-up Clinical CRF for all patients throughout the study.

At the start of patient enrollment, Evidera will provide each clinical site with Participant Packets for all study participants. Each packet will be labeled with a unique participant identification (ID) number, and all forms included in the packet will have headers pre-populated with the same unique participant ID number. The packet will include the Patient

Verbal Informed Consent Script, which includes consent/assent documentation, the AIRQ™, the Clinical CRF, which includes the Assess component of the Asthma Checklist (page 1 only), the AIRQ™ 3-month Recall, and the Follow-up Clinical CRF, which includes the Assess component of the Asthma Checklist (page 1). Note that the Assess component of the Asthma Checklist is mandatory for this study, while the Adjust and Review Responses component of the Asthma Checklist (pages 2-3) will be used at the discretion of the HCP. The AIRQ™ 3-month Recall and the Follow-up Clinical CRF will be paper clipped and printed on yellow paper to differentiate these two follow-up forms from the baseline forms that are completed during the initial visit. The patient will complete the AIRQ™ before seeing their HCP at the initial visit (telehealth or in-person), and the AIRQ™ 3-month Recall before seeing their HCP at the follow-up visit (telehealth or in-person). Training will be provided to sites on options available for administering the AIRQ™ (i.e., digital vs paper formats).

Before or during the initial visit, a clinical site staff member will introduce the study to the patient using the Patient Verbal Informed Consent Script. The scripts provide an overview of the purpose and nature of the study and will be used to obtain verbal consent from the patient/guardian, as well as assent from those participants under the age of 18 years. For patients 18 years or older, the site will document that the patient provided verbal consent. For patients aged 13-17 years, the site will document that the parent/guardian has granted consent and that the patient has provided assent. The clinical site staff will document patient eligibility and interest using the Recruitment Tracking Log (Appendix Y), including documentation of the number of patients who choose not to participate or are ineligible.

Once the patient has provided verbal consent/assent to the clinical site staff to participate in this study, and the clinical site staff has documented that the patient has provided consent/assent (Patient Verbal Informed Consent Screening Script), the clinical staff will ensure that the patient completes the AIRQ™ before seeing the HCP. After the questionnaire has been completed, clinical staff will ask the participant if they would be willing to complete an additional brief survey following their visit and at 3-months. If participants agree to complete the additional survey, the clinical staff will enter the patient's email address into a database at YouGov so that YouGov may send a survey link to the participant within 48 hours of enrollment (English Version: Appendix Z; Spanish Version: Appendix AA). The survey link will include the following questionnaires: the ACE Questionnaire, [redacted] and the Patient Sociodemographics Questionnaire. Participants will be asked to complete the survey within seven (7) days. Up to two email reminders will be sent to participants who have yet to complete the survey within approximately one week (7 days) of receiving the initial e-mail with the survey link (English Version: Appendix BB; Spanish Version: Appendix CC).

The clinical site will be responsible for completing a Clinical CRF, which also includes the assessment content of the Asthma Checklist (page 1), the AIRQ™, and the Follow-up Clinical CRF with each participant. All patient materials (e.g., questionnaires, resources) will be available in both English and Spanish.

Upon completion of the AIRQ™, the clinical staff member will provide **ALL** materials in the enrollment packet to the HCP conducting the clinical visit (telehealth or in-person). The HCP will review the AIRQ™ results and total score during the clinic visit. If the HCP feels it is appropriate, he/she may discuss with the patient his/her responses to individual screener questions. The HCP will then use the AIRQ™ results in conjunction with the Asthma Checklist and education materials (PRECISION program) with the patient to guide the discussion of the patient's asthma assessment, management, and treatment plan. Following the clinic visit (telehealth or in-person), the HCP and site staff will complete the Clinical CRF, which also includes responses to the Assess component of the Asthma Checklist and documentation of study eligibility and consent.

If a follow-up patient clinic visit occurs after the initial visit, the site staff/HCP will be asked to ensure that the participant completes the AIRQ™ 3-month Recall, using the same procedures as the initial telehealth visit. A Follow-up CRF form will also be completed during this visit. Note that patients will not be asked to complete additional questionnaires at the follow-up visit.

The study team originally planned to collect exacerbation data to compare 12 months pre-initial visit to 12 months post-initial visit among patients from third-party payer sites. However, these sites were unable to participate in the study. Therefore, high performing sites were selected to recontact their participants to ask if they would be willing to participate in a chart review to be conducted 12 months after their initial study visit. If patients agree, sites will use a new verbal consent script specific for the 12-month post-initial visit exacerbation data. For patients who consent, the site will complete a 12-month post-initial visit exacerbation CRF form. Data will only be collected for patients who provide their verbal consent. Verbal consent will be documented on the 12-month post-initial visit exacerbation CRF form. This will be compared to the exacerbation data 12 months pre-initial visit, which was collected as part of the planned clinician-completed CRF form. Evidera will host a 30-minute conference call with each clinical site for up to four (4) time points (touchpoints) at Months 1, 2, 3 (optional), and 6 to discuss the use of the PRECISION tools, address site questions, and discuss a set of touchpoint questions that focus on the challenges and facilitators of implementing the PRECISION program. These meetings will also be used to identify any sites that may benefit from participating in a re-training session (budget assumes up to six sites will need re-training). The optional month three (3) touchpoint will be based on whether the site is having any difficulties with the study.

After patient enrollment has been completed, prescribing providers at clinical sites, nurse case managers, or the asthma coaches from the telehealth component of Asthma and Allergy Network who treated at least 10 patients will complete the Post-study Survey. Evidera will provide the participating HCP with Post-study Survey, via an email PDF attachment (to be self-completed by the HCP). The emailed survey will have a pre-populated header with a unique participant ID number.

Approximately nine months following study implementation, Evidera will conduct telephone interviews with key staff and site principal investigators (up to three staff members per site). Interviews will follow a semi-structured interview guide to elicit from participating HCPs the advantages and disadvantages of implementing AIRQ™ in their clinic, their process for implementing these tools, what could be improved to facilitate implementation, and any unforeseen potential effects of implementing these tools. Interviews will be conducted via telephone and are expected to last approximately 60 minutes. Interviews will be audio-recorded and transcribed.

Patients will complete the following measures:

- AIRQ™ 12M
- AIRQ™ 3-Month Recall (as appropriate)
- ACE Questionnaire (for those who agree; initial visit only)
- CCI
- Patient Sociodemographics Questionnaire (for those who agree; initial visit only)

HCPs will complete the following measures:

- Clinical CRF
- Follow-up Clinical CRF (if appropriate)
- Clinal Site Touchpoint Questions
- Post-study Survey
- Qualitative Interview
- 12-month Post-Initial Visit Exacerbation CRF (when applicable)

6.1.3 Quality Control

6.1.3.1 Responsibilities

Evidera Responsibilities	Clinical Site Responsibilities	Website Host Responsibilities
Contract directly with clinical sites	Complete and return all institutional review board (IRB)-required documentation to Evidera, as needed	

Evidera Responsibilities	Clinical Site Responsibilities	Website Host Responsibilities
Develop and provide to sites all necessary IRB materials and forms for the patient screening process	Participate in a 60-minute training session about the study, conducted by Evidera	
Submit IRB paperwork on behalf of the sites to the central IRB, or assist sites with local IRB submissions	Ensure that appropriate training has been provided for all staff involved in the study	
Collect, monitor, and store data using DataFax—a direct fax-to-computer (or PDF-to-computer) data management system	Maintain patient confidentiality; Enter patient's email address into the YouGov[3] system on the day of recruitment	
Develop training materials for the training sessions for relevant site investigators and coordinators before study launch	Recruit and screen patients using the Verbal Informed Consent and Recruitment Scripts provided, and obtain verbal consent/assent	
Continually monitor patient recruitment	Track recruitment efforts in the Recruitment Training Log	
Remunerate sites	Provide Evidera project staff with weekly updates on screening and recruitment progress	
Contact sites for data queries on completed or missing forms	Ensure that all necessary questionnaires and forms are completed	Host the study website which includes the Asthma checklist and educational materials, as well as maintain and track all views to the site (i.e., number of time the HCP clicks/PDF views the Asthma Checklist and educational resources)
Lead study closeout procedures, with the help of clinical site staff (e.g., closing out the study with the IRB)	Complete Clinical CRFs for all enrolled patients after interest has been obtained	
Statistical analyses	Designate one staff member to be Evidera's point of contact during implementation, and provide Evidera with that person's direct telephone number	
Adverse event (AE) reporting of AstraZeneca products	Promptly respond to data queries from Evidera	
	Maintain appropriate and confidential project files	

Evidera Responsibilities	Clinical Site Responsibilities	Website Host Responsibilities
	Adhere to all site-related procedures outlined in the protocol	
	Perform required study closeout procedures	
	AE reporting (as outlined in section 6.3)	

Monitoring

Before the first subject is recruited into the study, Evidera will perform the following activities:

- Establish the investigator's capability to appropriately select the sample
- Discuss with the investigator(s) (and other personnel involved in the study) their responsibilities with regards to protocol compliance, and the responsibilities of AstraZeneca or its representatives; this will be documented in a Study Primary Agreement or equivalent between AstraZeneca/delegate and the investigator.

Evidera can implement different activities to ensure compliance with AstraZeneca standards of quality. These activities could include but are not limited to:

Contact the sites to:

- Provide information and support to the investigator(s)
- Confirm that the research team is complying with the protocol, and that data are being accurately recorded in the CRFs
- Ensure that the consent/assent documentation portion of the eligibility section of the Clinical CRF are signed, and screening scripts are stored at the investigator's site
- Ensure that the CRFs are completed properly and with adequate quality

Monitor activities for:

- Ensuring that consent/assent is documented in Patient Verbal Informed Consent Script and the Clinical CRF
- Evidera will host a 30-minute conference call with each clinical site for up to four (4) time points (touchpoints) at Months 1, 2, 3 (optional), and 6 to address site questions, and discuss a set of touchpoint questions that focus on the challenges and facilitators of implementing the PRECISION Tools.

Training of Study Site Personnel

The principal investigator will ensure that appropriate training relevant to the study is given to investigational staff and that any new information relevant to the performance of this study is forwarded to the staff involved.

6.1.3.2 ePRO Programming and Hosting

A Health Insurance Portability and Accountability Act (HIPAA)-compliant vendor specializing in electronic data capture will be responsible for the programming and hosting of the electronic patient-reported outcome (ePRO) data management system to collect and monitor data captured by the patient questionnaires. The quality assurance process will include extensive end-to-end testing, as well as a pre-test of data export and tabulations before launching with a live sample. During data collection, the web survey responses will be tracked by unique participant identifiers—not participant names.

Quantitative data from the clinical CRF will be transmitted via a secure SharePoint site directly into the electronic system database, DataFax. Data discrepancies will be identified and resolved.

6.1.3.3 DataFax CRF and Database Setup

The AIRQ™, the AIRQ™ 3-month Recall, Clinical CRF (which includes eligibility and consent documentation and the Asthma Checklist Assess content), the Follow-up Clinical CRF, and the Post-study Survey will be collected and managed using the DataFax system, according to Evidera's standard operating procedures (SOPs). Before data collection, data verification guidelines regarding out-of-range values, inconsistent responses, and data checks will be developed; and a testing of the DataFax system will be conducted.

CRF data will be optically entered into the study database upon transmittal via DataFax; once received, each CRF will be processed and reviewed by two trained project team members. The first-level reviewer will review all CRFs, while the second-level reviewer will review any items the first-level reviewer flagged or queried. Discrepancies or queries that are not resolved by the data entry staff will be forwarded to the sites for resolution.

6.1.3.4 Database Management

A database for all quantitative data collected in the interviews from the paper-completed questionnaires (e.g., AIRQ™, Clinical CRF) will be developed, tested, and validated using DataFax software. DataFax is a direct fax-to-computer (or PDF-to-computer) data management system that uses optical character recognition (OCR) software for collecting study CRFs that are sent directly into the system. DataFax is a Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (CFR) Part 11 Compliant system that provides a time-stamped electronic audit trail for the creation, modification, or deletion of electronic data, and is required for studies seeking FDA regulatory submission.

6.2 Protection of Human Subjects

This community program intervention study will be performed following ethical principles that are consistent with the Declaration of Helsinki, International Council for Harmonisation (ICH), Good Clinical Practices (GCPs), and the applicable legislation on non-interventional and/or community program interventional studies.

The investigator will perform the community program intervention study in accordance with the regulations and guidelines governing medical practice and ethics in the study's country, and in accordance with currently acceptable techniques and know-how.

The final community program intervention study protocol, including the final version of the subject Informed Consent Form, must be approved or given a favorable opinion in writing by the ethics committee/institutional review board (IRB)/independent ethics committee (IEC).

The ethics committee/IRB/IEC must also approve any amendment to the protocol and all advertising used to recruit subjects for the study, according to local regulations.

6.2.1 Patient Informed Consent

Clinical site staff will be responsible for ensuring that each participant is given full and adequate oral information about the study's nature, purpose, procedures, risks, and benefits. Participants will also be notified that they are free to withdraw from the study at any time. Participants will also be informed that, should they choose not to participate in all or any part of the study, their current or future treatment at the site will not be affected. Participants will be given the opportunity to ask questions and allowed time to consider the information provided. Participants will be required to provide verbal consent/assent to participate in the study. Clinical site staff will be responsible for documenting patient consent/assent by initialing and dating the patient verbal informed consent/assent. Script, documenting eligibility and consent in the Clinical CRF, and acknowledging that the patient agreed to participate in the study.

The participant's verbal consent (adults or parent/guardians) and verbal assent from minors must be obtained and documented before any specific procedures for this implementation study are performed, including:

- Administering the AIRQ^{TM}
- Obtaining email address for follow-up questionnaires
- Completing the Clinical CRFs

The Investigator must store the original Patient Verbal Informed Consent script documenting verbal consent/assent in a secure locked location.

This study involves participant-completed measures for information purposes only; the study does not involve the use of an investigational drug or device. There are no known risks or benefits to participants. During or following the research study, patients may become more aware of how they feel about their condition—and how their condition may affect certain aspects of their lives. Patients will be encouraged to talk with their asthma provider about their questions or concerns. The elements of federal regulations about consent procedures, disclosure of potential risks and benefits, and patient confidentiality will be strictly observed.

6.2.2 Health Care Practioner and Key Clinical Site Staff Informed Consent

Health care practitioners (HCPs) (e.g., doctor, specialist, nurse practitioner, pharmacist, asthma educator, care coordinator, physician assistant) and key clinical site staff (e.g., site coordinator) will be provided full and adequate written information before consenting to participate in the Post-study Survey and full and adequate oral information before participating in the semi-structured interviews about the nature, purpose, procedures, risks, and benefits of the survey and interview. HCPs/key clinical site staff participants will also be notified that they are free to withdraw from participating in the survey or interview at any time. Participants will also be informed that, should they choose not to participate in all or any part of the survey or interview, their current or future employment at the site will not be affected. HCPs/key clinical site staff participants will be given an opportunity to ask questions and given time to consider the information provided. Before completing the Post-study Survey, HCPs will consent to participate in the study by ticking a box that indicates that, by completing and returning the form, they are voluntarily agreeing to take part in the survey. HCPs/key clinical site staff participating in the semi-structured interviews will be required to provide verbal consent to participate in the interview. Research staff will be responsible for documenting the HCP and key clinical site staffs' verbal consent by initialing and dating the HCP/key clinical site staffs' verbal informed consent in the verbal consent script.

The Researchers must store the original HCP/key clinical site staff Written (for Post-study Surveys) and Verbal Informed Consent (for qualitative interviews) scripts documenting consent in a secure locked location.

6.2.3 Confidentiality of Study/Participant Data

All data collected will be strictly confidential, in accordance with local, state, and federal law. Personnel from the following organizations may examine the research study records: Evidera, AstraZeneca and its affiliates, and regulatory agencies (such as the FDA and the IRB). Only clinical site study staff involved in participant recruitment, clinical data extraction, and questionnaire administration will know the identities of patients. Staff will be instructed to maintain complete confidentiality of all collected data. Participant data files collected by clinical sites and shared with either Evidera or AstraZeneca will be kept in a locked file

cabinet separate from their identifying information and will be destroyed per Evidera's SOPs after a period of 15 years. The summary report generated from the completed questionnaires will not contain any participant-identifying information. Medical data collected will not be associated with personal health identification data. All study data will be de-identified.

Evidera retains records for a minimum of two years on-site, and an additional five years off-site. Upon enrollment, participants will be assigned unique ID numbers, which will be used to track participants throughout the study. Only the unique participant ID numbers and participant initials will be entered into the database and recorded on the participant questionnaires—not participant names.

This descriptive study will be performed in accordance with ethical principles that are consistent with the Declaration of Helsinki, ICH, GCP, and the applicable legislation on community program intervention studies.

The investigators will perform this descriptive study in accordance with the regulations and guidelines governing medical practice and ethics in the descriptive study's country, and in accordance with currently acceptable techniques and know-how.

The final descriptive study protocol must be approved or given a favorable opinion in writing by the ethics committee/IRB/IEC.

The ethics committee/IRB/IEC must also approve any protocol amendment and all advertising used to recruit subjects for the study, according to local regulations.

6.3 Collection and Reporting of Adverse Events/Adverse Drug Reactions

This is a community program intervention study, with no requirements to actively collect AEs during the study, since study enrollment is based on disease diagnosis and does not require the administration of an AZ drug. However, if an investigator (or patient) would like to report an AE that is not required to be collected, this can be reported as a spontaneous report according to local regulations and procedures.

It is also not required to report potential AEs based on answers to the following patient-completed assessments: AIRQ™, AIRQ™ 3-month Recall, CCI and ACE™.

The rationale is:

a. The signs and symptoms collected by these instruments are prevalent among asthmatic patients. It is not feasible to evaluate associations between a specific drug and events

reported by patients based on these instruments, due to a lack of baseline disease information and a temporal relationship of drug and event.

Patients will be informed that their healthcare providers (including clinic study staff and their clinicians) may not be reviewing their responses to the study questionnaires in real-time. They will be instructed to report any health concerns or issues that they may experience directly to their healthcare providers.

7. LIST OF REFERENCES

Expert Panel Working Group of the National Heart Lung Blood Institute, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. *J Allergy Clin Immunol*. 2020;146(6):1217-1270.

CCI [redacted].

CCI [redacted]

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Murphy KR, Chipps B, Beuther DA, et al. Development of the Asthma Impairment and Risk Questionnaire (AIRQ): A Composite Control Measure. *J Allergy Clin Immunol Pract*. 2020;8(7):2263-2274 e2265.

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Nunes C, Pereira AM, Morais-Almeida M. Asthma costs, and social impact. *Asthma Res Pract*. 2017;3:1.

CCI [redacted]

APPENDIX A. PATIENT VERBAL INFORMED CONSENT SCRIPTS (FOR ≥ 18 YEARS) (ENGLISH VERSION)

APPENDIX B. PATIENT VERBAL INFORMED CONSENT SCRIPTS (FOR ≥ 18 YEARS) (SPANISH VERSION)

Placeholder

APPENDIX C. PATIENT VERBAL INFORMED ASSENT/CONSENT SCRIPTS (FOR < 18 YEARS) (ENGLISH VERSION)

APPENDIX D. PATIENT VERBAL INFORMED CONSENT SCRIPTS (FOR < 18 YEARS) (SPANISH VERSION)

Placeholder

APPENDIX E. AIRQ™ (ENGLISH VERSION)

PRECISION

Asthma Impairment and Risk Questionnaire (AIRQ™)

For use by health care providers with their patients 12 years and older who have been diagnosed with asthma. AIRQ™ is intended to be part of an asthma clinic visit.

Please answer all of the questions below.

In the past 2 weeks, has coughing, wheezing, shortness of breath, or chest tightness:

1. Bothered you during the day on **more than 4 days**? Yes / No
2. Woke you up from sleep **more than 1 time**? Yes / No
3. Limited the activities you want to do **every day**? Yes / No
4. Caused you to use your rescue inhaler or nebulizer **every day**? Yes / No

Primatene® MIST (Amphastar Pharmaceuticals) or Epinephrine | ProAir® HFA (Teva Respiratory, LLC) or Albuterol sulfate | ProAir RespiClick® (Teva Respiratory, LLC) or Albuterol sulfate | Proventil® HFA (Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.) or Albuterol sulfate | Ventolin® HFA (GlaxoSmithKline) or Albuterol sulfate | Xopenex HFA® (Sunovion Pharmaceuticals Inc.) or Levalbuterol tartrate | Albuterol sulfate or Xopenex® (Sunovion Pharmaceuticals Inc.) or Levalbuterol HCl

Please see all prescribing information for all products.

In the past 2 weeks:

5. Did you have to limit your social activities (such as visiting with friends/relatives or playing with pets/children) because of your asthma? Yes / No
6. Did coughing, wheezing, shortness of breath, or chest tightness limit your ability to exercise? Yes / No
7. Did you feel that it was difficult to control your asthma? Yes / No

In the past 12 months, has coughing, wheezing, shortness of breath, or chest tightness:

8. Caused you to take steroid pills or shots, such as prednisone or Medrol®*? Yes / No
9. Caused you to go to the emergency room or have unplanned visits to a health care provider? Yes / No
10. Caused you to stay in the hospital overnight? Yes / No

Total YES Answers ☐

What Does My AIRQ™ Score Mean?

The AIRQ™ is meant to help your health care providers talk with you about your asthma control. The AIRQ™ does not diagnose asthma. Whatever your AIRQ™ score (total **YES** answers), it is important for your health care team to discuss the number and answers to each of the questions with you. All patients with asthma, even those who may be well-controlled, can have an asthma attack. As asthma control worsens, the chance of an asthma attack increases.[1] Only your medical provider can decide how best to assess and treat your asthma.

*Medrol® (Pfizer, Inc.) or methylprednisolone

The trademarks depicted above are the property of their respective owners.

[1]Global Strategy for Asthma Management and Prevention: ©2020 Global Initiative for Asthma

APPENDIX F. AIRQ™ (SPANISH VERSION)

[redacted]

Participant ID ☐☐☐ ☐☐☐ Verification Code ☐☐☐ Date ☐☐ DD ☐☐☐ MMM 20☐☐ YYYY

PRECISION

Cuestionario sobre la afectación y el riesgo en el asma (AIRQ™)

Para uso de los proveedores de atención médica con sus pacientes mayores de 12 años que hayan sido diagnosticados de asma. El AIRQ™ está diseñado para formar parte de una visita a una clínica de asma.

Por favor, responda todas las preguntas a continuación.

En las últimas dos semanas, la tos, la sibilancia, la dificultad para respirar o la presión en el pecho:

1. ¿Le molestaron en el transcurso del día durante **más de cuatro días**? Sí No
2. ¿Lo despertaron **más de una vez**? Sí No
3. ¿Limitaron las actividades que desea realizar **todos los días**? Sí No
4. ¿Hicieron que tuviera que usar su inhalador de rescate o nebulizador **todos los días**? Sí No

Por favor, consulte la ficha técnica completa de todos los productos.

En las últimas dos semanas:

5. ¿Tuvo que limitar sus actividades sociales (como visitar a amigos/parientes o jugar con mascotas/niños) debido a su asma? Sí No
6. ¿La tos, la sibilancia, la dificultad para respirar o la presión en el pecho limitaron su capacidad de hacer ejercicio? Sí No
7. ¿Sintió que era difícil controlar su asma? Sí No

En los últimos 12 meses, la tos, la sibilancia, la dificultad para respirar o la presión en el pecho:

8. ¿Hicieron que tuviera que usar pastillas o inyecciones de corticosteroides, como prednisona o Medrol®*? Sí No
9. ¿Hicieron que tuviera que ir a una sala de emergencias o consultas no planificadas con un proveedor de atención médica? Sí No
10. ¿Hicieron que tuviera que permanecer en el hospital durante la noche? Sí No

Total de respuestas "Sí" ☐

¿Qué significa mi puntuación AIRQ™?

El AIRQ™ tiene como objetivo ayudar a sus proveedores de atención médica a hablar con usted sobre el control de su asma. El AIRQ™ no diagnostica el asma. Cualquiera que sea su puntuación de AIRQ™ (total de respuestas **afirmativas**), es importante que su equipo de atención médica converse con usted acerca del número que obtenga y las respuestas a cada una de las preguntas. Todos los pacientes con asma, incluso aquellos que podrían estar bien controlados, pueden tener una crisis asmática. A medida que el control del asma empeora, la probabilidad de sufrir una crisis asmática aumenta.1 Solamente su proveedor médico puede decidir la mejor manera de evaluar y tratar su asma.

*Medrol® (Pfizer, Inc.) o metilprednisolona; las marcas registradas que se muestran son propiedad de sus respectivos dueños.

†Estrategia mundial para el tratamiento y la prevención del asma. ©2020 Iniciativa mundial para el asma

APPENDIX G. AIRQ™ 3-MONTH RECALL (ENGLISH VERSION)

[redacted]

Participant ID ☐☐☐ ☐☐☐ Verification Code ☐☐☐ Date ☐☐ DD ☐☐☐ MMM 20☐☐ YYYY

Asthma Impairment and Risk Questionnaire (AIRQ™)

For use by health care providers with their patients 12 years and older who have been diagnosed with asthma. AIRQ™ is intended to be part of an asthma clinic visit.

Please answer all of the questions below.

In the past 2 weeks, has coughing, wheezing, shortness of breath, or chest tightness:

1. Bothered you during the day on **more than 4 days**? Yes No
2. Woke you up from sleep **more than 1 time**? Yes No
3. Limited the activities you want to do **every day**? Yes No
4. Caused you to use your rescue inhaler or nebulizer **every day**? Yes No

Primatene® MIST (Amphastar Pharmaceuticals) or Epinephrine | ProAir HFA (Teva Respiratory, LLC) or Albuterol sulfate | ProAir RespiClick® (Teva Respiratory, LLC) or Albuterol sulfate | Proventil® HFA (Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.) or Albuterol sulfate | Ventolin® HFA (GlaxoSmithKline) or Albuterol sulfate | Xopenex HFA® (Sunovion Pharmaceuticals Inc.) or Levalbuterol tartrate | Albuterol sulfate or Xopenex® (Sunovion Pharmaceuticals Inc.) or Levalbuterol HCl

Please see all prescribing information for all products.

In the past 2 weeks:

5. Did you have to limit your social activities (such as visiting with friends/relatives or playing with pets/children) because of your asthma? Yes No
6. Did coughing, wheezing, shortness of breath, or chest tightness limit your ability to exercise? Yes No
7. Did you feel that it was difficult to control your asthma? Yes No

In the past 3 months, has coughing, wheezing, shortness of breath, or chest tightness:

8. Caused you to take steroid pills or shots, such as prednisone or Medrol®*? Yes No
9. Caused you to go to the emergency room or have unplanned visits to a health care provider? Yes No
10. Caused you to stay in the hospital overnight? Yes No

Total YES Answers ☐

What Does My AIRQ™ Score Mean?

The AIRQ™ is meant to help your health care providers talk with you about your asthma control. The AIRQ™ does not diagnose asthma. Whatever your AIRQ™ score (total **YES** answers), it is important for your health care team to discuss the number and answers to each of the questions with you. All patients with asthma, even those who may be well-controlled, can have an asthma attack. As asthma control worsens, the chance of an asthma attack increases. Only your medical provider can decide how best to assess and treat your asthma.

*Medrol® (Pfizer, Inc.) or methylprednisolone. The trademarks depicted above are the property of their respective owners.

†Global Strategy for Asthma Management and Prevention: ©2020 Global Initiative for Asthma

APPENDIX H. AIRQ™ 3-MONTH RECALL (SPANISH VERSION)

Participant ID ☐☐☐ ☐☐☐   Verification Code ☐☐☐   Date ☐☐ DD ☐☐☐ MMM 20☐☐ YYYY

Cuestionario sobre la afectación y el riesgo en el asma (AIRQ™)

Para uso de los proveedores de atención médica con sus pacientes mayores de 12 años que hayan sido diagnosticados de asma. El AIRQ™ está diseñado para formar parte de una visita a una clínica de asma.

Por favor, responda todas las preguntas a continuación.

En las últimas dos semanas, la tos, la sibilancia, la dificultad para respirar o la presión en el pecho:

1. ¿Le molestaron en el transcurso del día durante **más de cuatro días**? Sí No
2. ¿Lo despertaron **más de una vez**? Sí No
3. ¿Limitaron las actividades que desea realizar **todos los días**? Sí No
4. ¿Hicieron que tuviera que usar su inhalador de rescate o nebulizador **todos los días**? Sí No

Por favor, consulte la ficha técnica completa de todos los productos.

En las últimas dos semanas:

5. ¿Tuvo que limitar sus actividades sociales (como visitar a amigos/parientes o jugar con mascotas/niños) debido a su asma? Sí No
6. ¿La tos, la sibilancia, la dificultad para respirar o la presión en el pecho limitaron su capacidad de hacer ejercicio? Sí No
7. ¿Sintió que era difícil controlar su asma? Sí No

En los últimos 3 meses, la tos, la sibilancia, la dificultad para respirar o la presión en el pecho:

8. ¿Hicieron que tuviera que usar pastillas o inyecciones de corticosteroides, como prednisona o Medrol®*? Sí No
9. ¿Hicieron que tuviera que ir a una sala de emergencias o consultas no planificadas con un proveedor de atención médica? Sí No
10. ¿Hicieron que tuviera que permanecer en el hospital durante la noche? Sí No

Total de respuestas "Sí" ☐

¿Qué significa mi puntuación AIRQ™?

El AIRQ™ tiene como objetivo ayudar a sus proveedores de atención médica a hablar con usted sobre el control de su asma. El AIRQ™ no diagnostica el asma. Cualquiera que sea su puntuación de AIRQ™ (total de respuestas **afirmativas**), es importante que su equipo de atención médica converse con usted acerca del número que obtenga y las respuestas a cada una de las preguntas. Todos los pacientes con asma, incluso aquellos que podrían estar bien controlados, pueden tener una crisis asmática. A medida que el control del asma empeora, la probabilidad de sufrir una crisis asmática aumenta.1 Solamente su proveedor médico puede decidir la mejor manera de evaluar y tratar su asma.

APPENDIX I. CLINICAL CASE REPORT FORM (CRF)

Evidera 138 Site Page 1 of 7

Evidera # 138 Plate # 001 Visit # 000

Participant ID ☐☐☐ ☐☐☐

Date of Visit ☐☐ DD ☐☐☐ MMM 20☐☐ YYYY

Clinical Case Report Form

Part 1. ELIGIBILITY

Please check **YES** or **NO** for each of the following criteria:

INCLUSION CRITERIA	YES	NO
1. ≥ 13 years of age at the time of enrollment	☐	☐
2. Prior diagnosis of physician confirmed asthma	☐	☐
3. Able to read, understand, and speak English or Spanish sufficiently to self-complete or be administered the AIRQ™ via telephone, desktop computer, or mobile device (e.g., smartphone, iPad)	☐	☐
4. Provide consent (adults/parents/guardians) and assent (age 13-17 years) to participate in the study	☐	☐

ALL of the above inclusion criteria questions must be **YES** for the patient to be eligible for inclusion.

EXCLUSION CRITERIA	YES	NO
1. Current diagnosis of active COPD or any lower respiratory diagnosis other than asthma.	☐	☐
2. Has a cognitive impairment, hearing difficulty, acute psychopathology, medical condition, or insufficient knowledge of the English or Spanish language that, in the opinion of the investigator, would interfere with his or her ability to agree to participate and/or complete the AIRQ™ or other study questionnaires	☐	☐

If **ANY** of the above answers to the exclusion criteria is **YES**, the patient is **NOT ELIGIBLE** for participation in this study.

The patient is eligible to participate in the study: ☐ **Yes** ☐ **No**

I certify that the above information is correct.

Investigator Signature: _____

Date: ☐☐ DD ☐☐☐ MMM 20☐☐ YYYY

Clinical Case Report Form EVA-26645-03 16 March 2021

Evidera # 138 Plate # 002 Visit # 001

Participant ID ☐☐☐ ☐☐☐

Date of Visit ☐☐ (DD) ☐☐☐ (MMM) 20☐☐ (YYYY)

Part 2. VERBAL CONSENT/ASSENT

For patients 13-17 years of age: Did the parent/guardian provide consent?
☐ Yes ☐ No ☐ N/A

For patients 13-17 years of age: Did the patient provide assent to participate?
☐ Yes ☐ No ☐ N/A

For patients ≥ 18 years of age: Did the patient provide verbal consent to participate?
☐ Yes ☐ No ☐ N/A

Initials of person obtaining consent/assent :_____

Date of consent/assent: ☐☐ (DD) ☐☐☐ (MMM) 20☐☐ (YYYY)

Part 3. CLINICAL INFORMATION

1. Platform used for appointment : ☐ telehealth ☐ in-person office visit

2. During the visit, how was the AIRQ™ administered?
   ☐ Interviewer ☐ Patient self-completed

3. During the visit, was the patient able to see their risk score on the ruler included in the AIRQ™?
   ☐ Yes ☐ No

   IF yes, how were patients able to view their risk score?
   ☐ On their phone
   ☐ On their computer
   ☐ Paper copy of AIRQ™ mailed to patient before the visit or provided at in-person visit
   ☐ Other, please specify: _____

4. Age (years): ☐☐

Evidera # 138 Plate # 003 Visit # 001

Participant ID

☐☐☐ ☐☐☐

5. Sex: ☐ male ☐ female ☐ non-binary ☐ Other:_____

6. How would you rate this patient's asthma severity?
   - ☐ Intermittent
   - ☐ Mild persistent
   - ☐ Moderate persistent
   - ☐ Severe persistent

7. Age of asthma diagnosis: ☐☐ ☐ Unknown

8. What is your assessment of the patient's overall asthma control?
   - ☐ Completely controlled
   - ☐ Well controlled
   - ☐ Somewhat controlled
   - ☐ Poorly controlled
   - ☐ Not controlled

9. Did the patient previously have COVID or do they currently have COVID?
   ☐ Yes ☐ No ☐ Unknown

10. What type of health insurance coverage does the patient have? (Check all that apply)
    - ☐ Third-party payer (for example, United Healthcare, Blue Cross/Blue Shield, Aetna)
    - ☐ Managed care organization
    - ☐ Tricare (military health insurance)
    - ☐ Affordable Care Act (ACA)
    - ☐ Medicare
    - ☐ Medicaid
    - ☐ Self-pay
    - ☐ None
    - ☐ Other (please specify): _____

11. Patient's state of residence: ☐☐

Evidera # 138 Plate # 004 Visit # 001

Participant ID

☐☐☐ ☐☐☐

12. Please indicate the medication the patient has taken for the past 3 months:

MAINTENANCE PHARMACOLOGIC THERAPY
*Please check **all** that apply.*

- ☐ **ICS only**
  - ☐ Low dose
  - ☐ Medium dose
  - ☐ High dose
- ☐ **ICS/LABA**
  - ☐ Low dose
  - ☐ Medium dose
  - ☐ High dose
- ☐ **LABA (Single inhaled medicine, not in a fixed-dose combination with an ICS or ICS/LAMA)**
- ☐ **LAMA (single inhaled medicine used with or without other inhaled therapies or alone)**
- ☐ **ICS/LABA/LAMA (fixed-dose combination)**
- ☐ **Leukotriene modifier**
- ☐ **Theophylline Preparations**
- ☐ **Macrolides Add-on Therapy**

Biologics

- ☐ Cinqair (reslizumab)
- ☐ Dupixent (dupilumab)
- ☐ Fasenra (benralizumab)
- ☐ Nucala (mepolizumab)
- ☐ Xolair (omalizumab)
- ☐ Other: _____

Rescue Therapy

- ☐ SABA alone with no maintenance therapy
- ☐ SABA with maintenance therapy
- ☐ Primatene Mist as a rescue and no maintenance therapy
- ☐ Primatene Mist as a rescue with maintenance therapy(s)
- ☐ ICS+SABA as rescue therapy alone
- ☐ ICS+SABA as rescue therapy with maintenance therapy(s)
- ☐ Fixed dose combination fast-acting LABA/ICS alone as rescue
- ☐ Fixed dose combination fast-acting LABA/ICS as rescue and maintenance therapy
- ☐ SABA as rescue therapy via nebulizer with other rescue or maintenance therapies
- ☐ SABA as rescue therapy via nebulizer without other rescue or maintenance therapies

Chronic Oral Corticoid Steroid Therapy

☐ Prednisone _____mg ☐ QD ☐ QOD

☐ **Other** (specify):_____

Note: please see Appendix DD for a description of drugs in each class listed above

Evidera # 138 Plate # 005 Visit # 001

Participant ID

13. Other health conditions (Please mark all boxes that apply with an "X.")

- ☐ **No other health conditions**
- ☐ Allergy diagnosed by blood or skin testing
- ☐ Allergic rhinitis (nasal allergies, "hay fever")
- ☐ Aeroallergens
- ☐ Heart disease (history of heart attack, heart failure, or heart valve problems)
- ☐ Anxiety
- ☐ Anaphylaxis (severe allergic reaction to a food, bee sting, allergy shot, medication, or other)
- ☐ Arthritis
- ☐ Aspirin sensitivity (aspirin causes hives, swelling, or breathing problems)
- ☐ Atopic dermatitis/Eczema
- ☐ Chronic bronchitis
- ☐ Chronic Obstructive Pulmonary Disease (COPD)
- ☐ Chronic sinusitis
- ☐ Depression
- ☐ Diabetes
- ☐ Emphysema
- ☐ GERD (heartburn/reflux)
- ☐ Hypertension (high blood pressure)
- ☐ Nasal Polyps
- ☐ Sleep Apnea
- ☐ Stroke
- ☐ Other (specify): _____
- ☐ **Unknown**

14. Was spirometry lung function testing performed on this patient in the last 12 months?

☐ Yes (Record below): Date of most recent spirometry ☐☐ (DD) ☐☐☐ (MMM) 20☐☐ (YYYY)

☐ No

Pre-bronchodilator

FVC: ☐.☐☐☐ L
☐☐☐ % (predicted)

FEV1: ☐.☐☐☐ L
☐☐☐ % (predicted)

FEV1/FVC ratio 0.☐☐

☐ Not Available

Post-bronchodilator

FVC: ☐.☐☐☐ L
☐☐☐ % (predicted)

FEV1: ☐.☐☐☐ L
☐☐☐ % (predicted)

FEV1/FVC ratio 0.☐☐

☐ Not Available

Evidera # 138 Plate # 006 Visit # 001

Participant ID

15. Please indicate asthma exacerbation history within the prior 12 months:

ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

15.1 Number of times in the past 12 months asthma symptoms **required an emergency department or urgent care visit (but not an overnight stay in the hospital):**

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

15.2 Number of times in the past 12 months that there was a worsening in asthma symptoms that **required a hospital stay for greater than 24 hours**:

☐☐ times admitted to hospital ☐ None

15.3 Number of unplanned ambulatory clinic visits due to exacerbation in past 12 months:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐
f. ☐☐ ☐☐☐ ☐☐☐☐

15.4 How many courses of oral corticosteroids (OCS) was the patient prescribed over the past 12 months for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma within 12 months
☐ 1 OCS course only for asthma within the past 12 months
☐ 2 OCS courses only for asthma within the past 12 months
☐ 3 OCS courses for asthma within the past 12 months
☐ ≥ 4 OCS courses for asthma within the past 12 months
☐ patient is on daily OCS

15.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Evidera # 138 Plate # 007 Visit # 001

Participant ID

☐☐☐ ☐☐☐

16. Following the use of the PRECISION program, which of the following will you do to the patient's medication after today's telehealth visit? (check all that apply)

- ☐ Step-down of controller medicines
- ☐ No change to the level of controller therapy
- ☐ Step-up of controller medicines
- ☐ Prescribe a course of systemic corticosteroids
- ☐ Begin work-up for possible biologic
- ☐ Begin biologic: (specify): _____
- ☐ Other: (specify): _____

Part 4. Asthma Checklist (Assess content only)

1. Please check the Asthma Checklist Assess items (page 1) that were considered during the visit:

CONSIDER FOR ALL PATIENTS REGARDLESS OF ASTHMA CONTROL

- ☐ Adherence[1-3]
- ☐ Appropriate Therapy[1,3]
- ☐ Asthma Action Plan[1,2,4]
- ☐ Inhaler Technique[1,2,4]
- ☐ Psychological Issues[1,2]
- ☐ Spirometry[1,2,4]
- ☐ Tobacco Use[1,2,5]
- ☐ Vaccinations[1,2,6,7]

CONSIDER FOR PATIENTS WITH UNCONTROLLED SYMPTOMS AND/OR RISK FACTORS FOR EXACERBATIONS

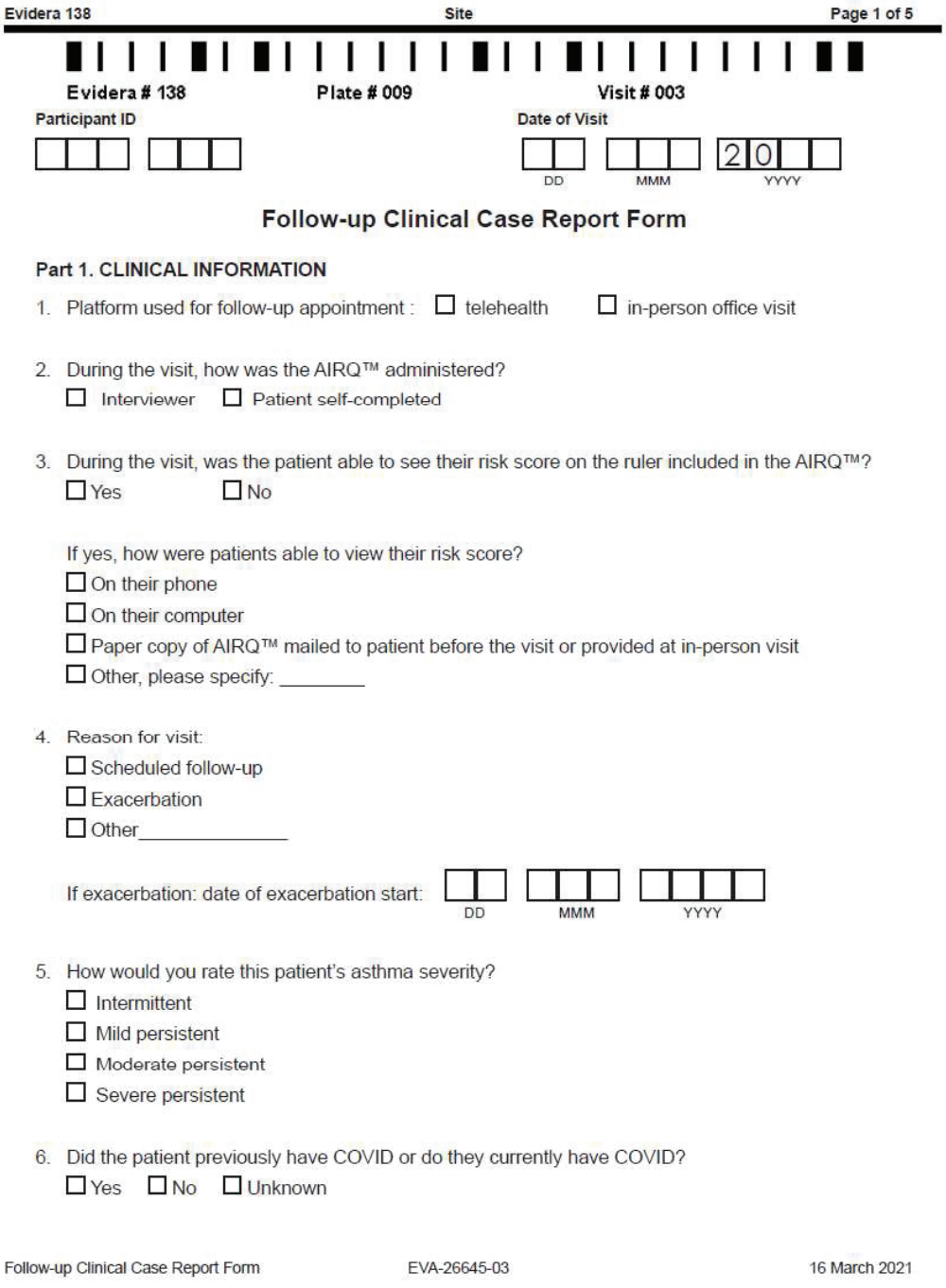
- ☐ Asthma Phenotyping[1-4]
- ☐ Comorbidities[1,2]
- ☐ Home and/or Work Exposures[1,2,4]
- ☐ Referral to an Asthma Specialty Center, or Other Appropriate Specialist or Health Care Provider in Your Area[1,2]
- ☐ Alternative Diagnoses and Hidden Comorbidities[1,2]
- ☐ Optimizing Therapy with Add-on or Advanced Treatment[1,3]

Investigator/Coordinator Signature: _____

Date: ☐☐ DD ☐☐☐ MMM 20☐☐ YYYY

APPENDIX J. FOLLOW-UP CRFS

Follow-up Clinical Case Report Form



Evidera 138 Site Page 1 of 5

Evidera # 138 Plate # 009 Visit # 003

Participant ID

Date of Visit DD MMM 20 YYYY

Follow-up Clinical Case Report Form

Part 1. CLINICAL INFORMATION

1. Platform used for follow-up appointment : ☐ telehealth ☐ in-person office visit

2. During the visit, how was the AIRQ™ administered?
   ☐ Interviewer ☐ Patient self-completed

3. During the visit, was the patient able to see their risk score on the ruler included in the AIRQ™?
   ☐ Yes ☐ No

   If yes, how were patients able to view their risk score?
   ☐ On their phone
   ☐ On their computer
   ☐ Paper copy of AIRQ™ mailed to patient before the visit or provided at in-person visit
   ☐ Other, please specify: _____

4. Reason for visit:
   ☐ Scheduled follow-up
   ☐ Exacerbation
   ☐ Other_____

   If exacerbation: date of exacerbation start: DD MMM YYYY

5. How would you rate this patient's asthma severity?
   ☐ Intermittent
   ☐ Mild persistent
   ☐ Moderate persistent
   ☐ Severe persistent

6. Did the patient previously have COVID or do they currently have COVID?
   ☐ Yes ☐ No ☐ Unknown

Follow-up Clinical Case Report Form EVA-26645-03 16 March 2021

Evidera # 138 Plate # 010 Visit # 003

Participant ID

☐☐☐ ☐☐☐

7. Please indicate all current medications and any changes that have occurred since the last study visit:

MAINTENANCE PHARMACOLOGIC THERAPY
*Please check **all** that apply.*

Please check all current medications the patient is taking

☐ **ICS only** ☐ Low dose ☐ Medium dose ☐ High dose ☐ **ICS/LABA** ☐ Low dose ☐ Medium dose ☐ High dose ☐ **LABA (Single inhaled medicine, *not* in a fixed-dose combination with an ICS or ICS/LAMA)** ☐ **LAMA (single inhaled medicine used with or without other inhaled therapies or alone)** ☐ **ICS/LABA/LAMA (fixed-dose combination)** ☐ **Leukotriene modifier** ☐ **Theophylline Preparations** ☐ **Macrolides Add-on Therapy** **Biologics** ☐ Cinqair (reslizumab) ☐ Dupixent (dupilumab) ☐ Fasenra (benralizumab) ☐ Nucala (mepolizumab) ☐ Xolair (omalizumab) ☐ Other: _____	**Rescue Therapy** ☐ SABA alone with no maintenance therapy ☐ SABA with maintenance therapy ☐ Primatene Mist as a rescue and no maintenance therapy ☐ Primatene Mist as a rescue with maintenance therapy(s) ☐ ICS+SABA as rescue therapy alone ☐ ICS+SABA as rescue therapy with maintenance therapy(s) ☐ Fixed dose combination fast-acting LABA/ICS alone as rescue ☐ Fixed dose combination fast-acting LABA/ICS as rescue and maintenance therapy ☐ SABA as rescue therapy via nebulizer with other rescue or maintenance therapies ☐ SABA as rescue therapy via nebulizer without other rescue or maintenance therapies

Chronic Oral Corticoid Steroid Therapy

☐ Prednisone _____mg ☐ QD ☐ QOD

☐ **Other** (specify):_____

Note: please see Appendix DD for a description of drugs in each class listed above

Evidera # 138 Plate # 011 Visit # 003

Participant ID ☐☐☐ ☐☐☐

8. Please indicate asthma exacerbation history since last visit:

ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

8.1 Number of times since the last visit that asthma symptoms required an emergency department or urgent care visit (but not an overnight stay in the hospital)):

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

8.2 Number of times since the last visit that there was a worsening in asthma symptoms that required a hospital stay for greater than 24 hours:

☐☐ times admitted to hospital ☐ None

8.3 Number of unplanned ambulatory clinic visits due to exacerbation since the last visit:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

☐ None

a. ☐☐ ☐☐☐ ☐☐☐☐
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐

8.4 How many courses of oral corticosteroids (OCS) was the patient prescribed since the last study visit for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma
☐ 1 OCS course only for asthma
☐ 2 OCS courses only for asthma
☐ 3 OCS courses for asthma
☐ ≥ 4 OCS courses for asthma
☐ patient is on daily OCS

8.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Evidera # 138 Plate # 012 Visit # 003

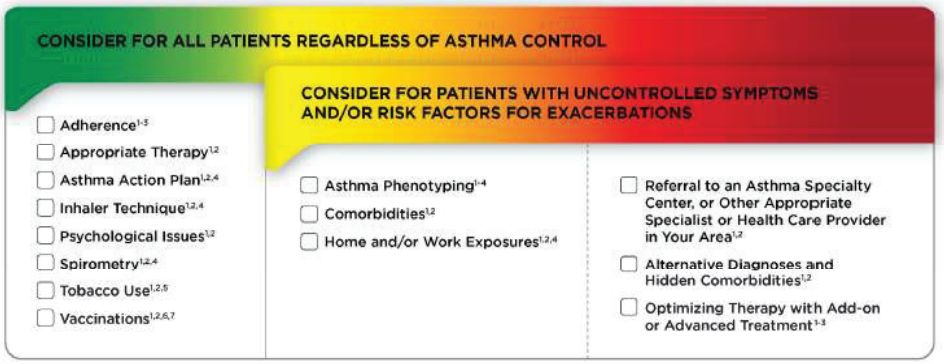
Participant ID

☐☐☐ ☐☐☐

9. What is your assessment of the patient's overall asthma control?
   - ☐ Completely controlled
   - ☐ Well controlled
   - ☐ Somewhat controlled
   - ☐ Poorly controlled
   - ☐ Not controlled

Part 2. Asthma Checklist (Assess content only)

1. Please check the Asthma Checklist Assess items (page 1) that were considered during the visit:



2. Following the use of the PRECISION program, which of the following will you do to the patient's medication after today's visit? (check all that apply)
   - ☐ Step-down of controller medicines
   - ☐ No change to the level of controller therapy
   - ☐ Step-up of controller medicines
   - ☐ Prescribe a course of systemic corticosteroids
   - ☐ Begin work-up for possible biologic
   - ☐ Begin biologic: (specify): _____
   - ☐ Other: (specify): _____

Evidera # 138 Plate # 013 Visit # 003

Participant ID

☐☐☐ ☐☐☐

For AAN and Third Party Payer Sites ONLY

1. Date of last coaching/follow-up session: ☐☐ DD ☐☐☐ MMM ☐☐☐☐ YYYY

2. Number of coaching/follow-up sessions: ☐☐

Investigator/Coordinator Signature: _____

Date: ☐☐ DD ☐☐☐ MMM 2☐☐☐ YYYY

12-Month Post-Initial Visit Exacerbation Clinical Case Report Form

Participant ID: ___ - ____

Verbal Consent Provided: ☐ Yes ☐ No

Date verbal consent provided: MM/DD/YYYY

Date form completed: MM/DD/YYYY

Please indicate the asthma exacerbation history since the patients initial study visit (12 months ago):

ASTHMA EXACERBATION HISTORY ☐ Not applicable

An asthma exacerbation is defined by a change in asthma control requiring a course of oral steroids (i.e., at least 3 days with at least 10 days between each burst) and/or steroid injection and/or a hospitalization for asthma or emergency department visit for an asthma exacerbation. **Importantly, record only the highest utilization for each exacerbation, do not double count exacerbation episodes. If an OCS course was due to a hospitalization, do not record as OCS course but as the hospitalization**

8.1 Number of times since the last visit that asthma symptoms required an emergency department or urgent care visit (but not an overnight stay in the hospital)):

☐☐ ER/urgent care visits (with no overnight hospital stay) ☐ None

8.2 Number of times since the last visit that there was a worsening in asthma symptoms that required a hospital stay for greater than 24 hours:

☐☐ times admitted to hospital ☐ None

8.3 Number of unplanned ambulatory clinic visits due to exacerbation since the last visit:

☐☐ unplanned visit—Please list dates of the most recent unplanned ambulatory clinic visit below (DD-MMM-YYY)

a. ☐☐ ☐☐☐ ☐☐☐☐ ☐ None
b. ☐☐ ☐☐☐ ☐☐☐☐
c. ☐☐ ☐☐☐ ☐☐☐☐
d. ☐☐ ☐☐☐ ☐☐☐☐
e. ☐☐ ☐☐☐ ☐☐☐☐

8.4 How many courses of oral corticosteroids (OCS) was the patient prescribed since the last study visit for asthma exacerbations unrelated to emergency department, urgent care or, unplanned ambulatory clinic visits or hospitalizations?

☐ 0 OCS courses for asthma
☐ 1 OCS course only for asthma
☐ 2 OCS courses only for asthma
☐ 3 OCS courses for asthma
☐ ≥ 4 OCS courses for asthma
☐ patient is on daily OCS

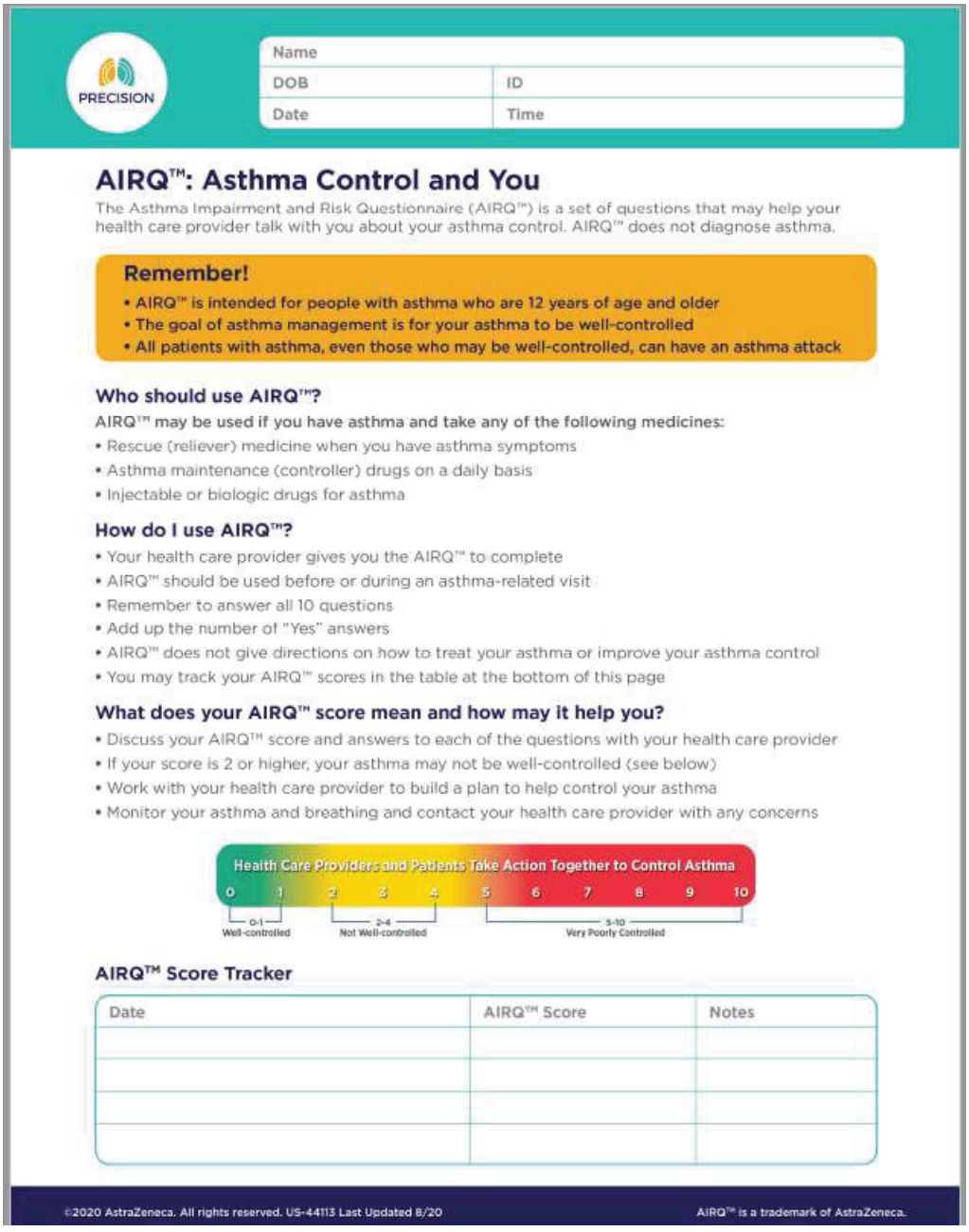
8.5 Date of most current exacerbation: ☐☐☐ (MMM) ☐☐☐☐ (YYYY) ☐ unknown

Investigator/Coordinator Signature: _____

APPENDIX K. PRECISION SUPPLEMENTAL ONLINE EDUCATIONAL RESOURCES

Patient Facing Tools

AIRQ™: Asthma Control and You (English Version)



PRECISION

Name	
DOB	ID
Date	Time

AIRQ™: Asthma Control and You

The Asthma Impairment and Risk Questionnaire (AIRQ™) is a set of questions that may help your health care provider talk with you about your asthma control. AIRQ™ does not diagnose asthma.

Remember!

- AIRQ™ is intended for people with asthma who are 12 years of age and older
- The goal of asthma management is for your asthma to be well-controlled
- All patients with asthma, even those who may be well-controlled, can have an asthma attack

Who should use AIRQ™?

AIRQ™ may be used if you have asthma and take any of the following medicines:

- Rescue (reliever) medicine when you have asthma symptoms
- Asthma maintenance (controller) drugs on a daily basis
- Injectable or biologic drugs for asthma

How do I use AIRQ™?

- Your health care provider gives you the AIRQ™ to complete
- AIRQ™ should be used before or during an asthma-related visit
- Remember to answer all 10 questions
- Add up the number of "Yes" answers
- AIRQ™ does not give directions on how to treat your asthma or improve your asthma control
- You may track your AIRQ™ scores in the table at the bottom of this page

What does your AIRQ™ score mean and how may it help you?

- Discuss your AIRQ™ score and answers to each of the questions with your health care provider
- If your score is 2 or higher, your asthma may not be well-controlled (see below)
- Work with your health care provider to build a plan to help control your asthma
- Monitor your asthma and breathing and contact your health care provider with any concerns

AIRQ™ Score Tracker

Date	AIRQ™ Score	Notes

AIRQ™: Asthma Control and You (Spanish Version)

PRECISION

Nombre	
Fecha de nacimiento	ID
Fecha	Hora

AIRQ™: El control del asma y usted

El cuestionario sobre el deterioro y el riesgo del asma (Asthma Impairment and Risk Questionnaire, AIRQ™) consiste en una serie de preguntas que pueden ayudar a su proveedor de cuidados de la salud a hablar con usted sobre el control del asma. El cuestionario AIRQ™ no diagnostica el asma.

¡Recuerde!

- **El cuestionario AIRQ™ está dirigido a personas con asma que tienen 12 años de edad o más.**
- **El objetivo del tratamiento del asma es que su asma esté bien controlada.**
- **Todos los pacientes con asma, incluso aquellos que están bien controlados, pueden tener un ataque de asma.**

¿Quién debe usar el cuestionario AIRQ™?

El cuestionario AIRQ™ puede utilizarse si tiene asma y toma cualquiera de los siguientes medicamentos:

- Medicamento de rescate (de alivio) cuando tiene síntomas de asma.
- Medicinas para el mantenimiento del asma (de control) todos los días.
- Medicinas inyectables o biológicas para el asma.

¿Cómo debo utilizar el cuestionario AIRQ™?

- Su proveedor de cuidados de la salud le dará el cuestionario AIRQ™ para que lo llene.
- El cuestionario AIRQ™ debe utilizarse antes de una visita relacionada con el asma o durante la misma visita.
- Recuerde responder las 10 preguntas.
- Sume el número de respuestas a las que haya contestado con "Sí".
- El cuestionario AIRQ™ no indica cómo tratar el asma ni cómo mejorar el control del asma.
- Puede realizar un seguimiento de sus puntuaciones en el cuestionario AIRQ™ en la tabla al final de esta página.

¿Qué significa su puntuación en el cuestionario AIRQ™ y cómo le puede ayudar?

- Hable sobre su puntuación y su respuesta a cada pregunta del cuestionario AIRQ™ con su proveedor de cuidados de la salud.
- Si su puntuación es de 2 o más, es posible que su asma no esté bien controlada (vea abajo).
- Trabaje con su proveedor de cuidados de la salud para crear un plan para el control de su asma.
- Monitoree su asma y respiración, y contacte a su proveedor de cuidados de la salud si tiene alguna preocupación.

Seguimiento de la puntuación en el cuestionario AIRQ™

Fecha	Puntuación en el cuestionario AIRQ™	Notas

Study Participant Education Printable Materials

Asthma and Other Health Conditions (English Version)


Appendix_Asthma and Other Health Con


Appendix_Asthma and Other Health Con


Appendix_Asthma and Other Health Con

Asthma and Spirometry Testing (English Version)


Appendix_Asthma and Spirometry Testir


Appendix_Asthma and Spirometry Testir


Appendix_Asthma and Spirometry Testir

Understanding Airway Inflammation in Asthma (English Version)


Appendix_Understanding Airway Inflamati


Appendix_Understanding Airway Inflamati


Appendix_Understanding Airway Inflamati

Asthma and Other Health Conditions (Spanish Version)

Placeholder

Asthma and Spirometry Testing (Spanish Version)

Placeholder

Understanding Airway Inflammation in Asthma (Spanish Version)

Placeholder

Patient Animations

Placeholder for all Animations, English, and Spanish

Asthma and Other Health Conditions (PDF Storyboard document)

Asthma and Spirometry Testing (PDF Storyboard document)

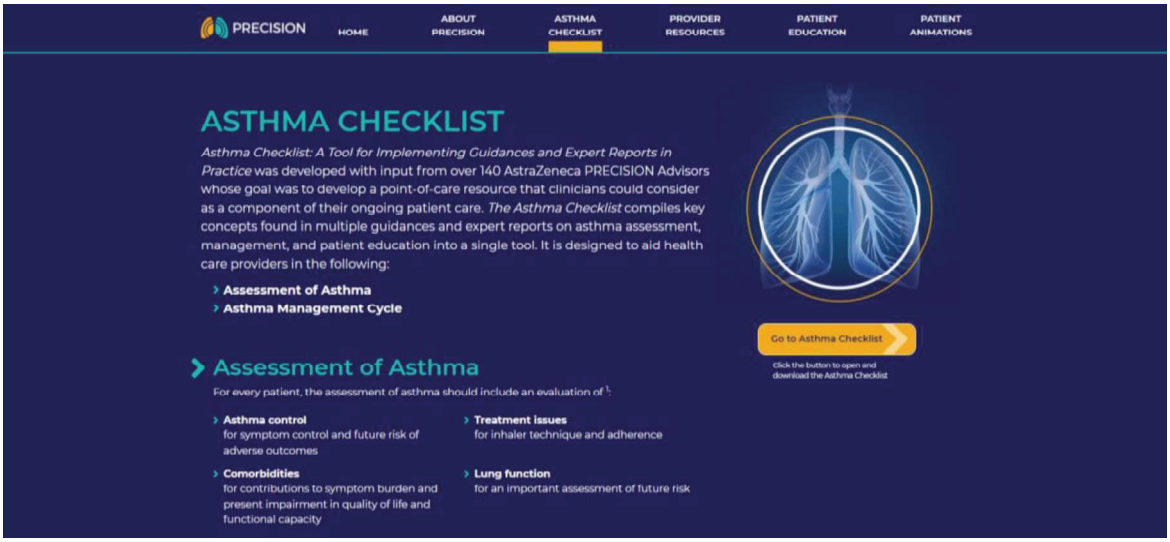
Understanding Airway Inflammation in Asthma (PDF Storyboard document)

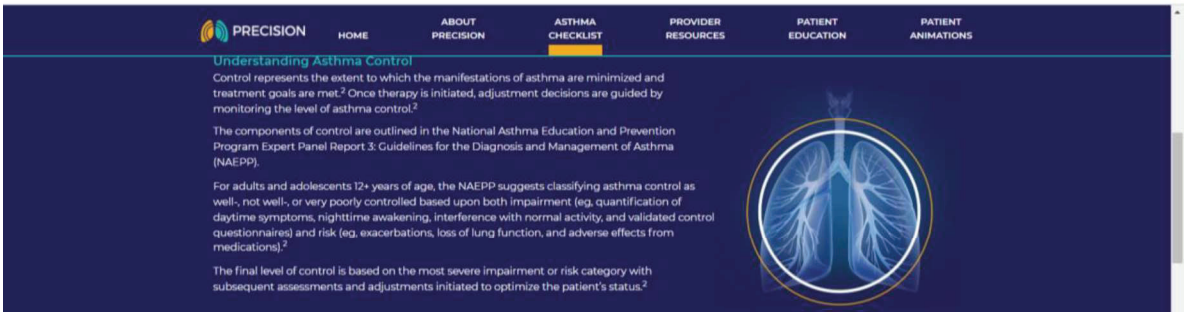
Using Your Pressurized Metered-Dose Inhaler (pMDI) (PDF Storyboard document and animation)

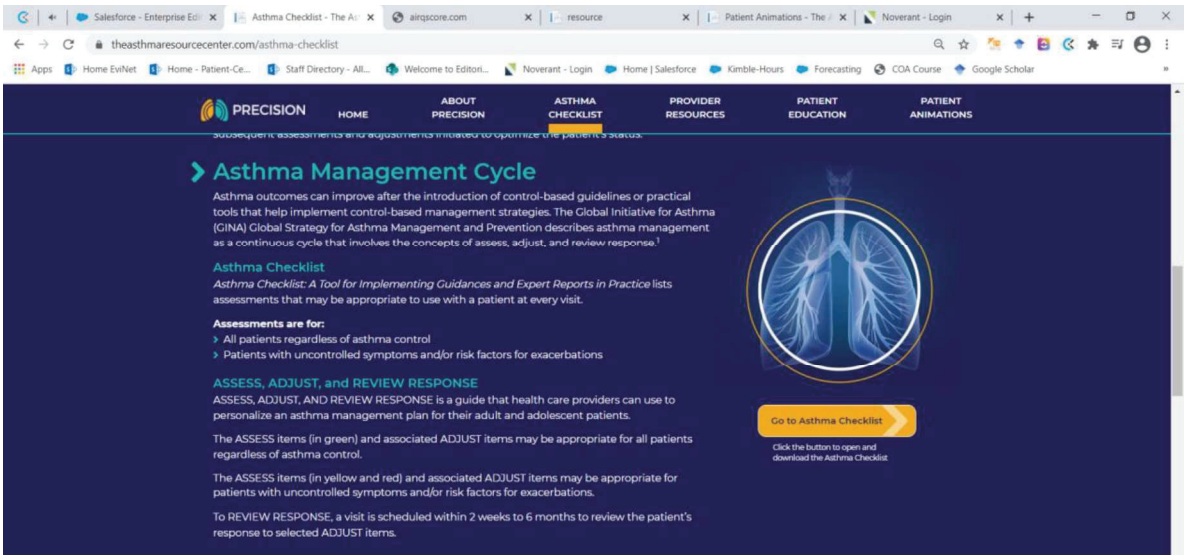
Using Your Pressurized Metered-Dose Inhaler (pMDI) With Spacer (PDF Storyboard document and animation)

Provider Facing Tools

Asthma Checklist - Intended Use Document



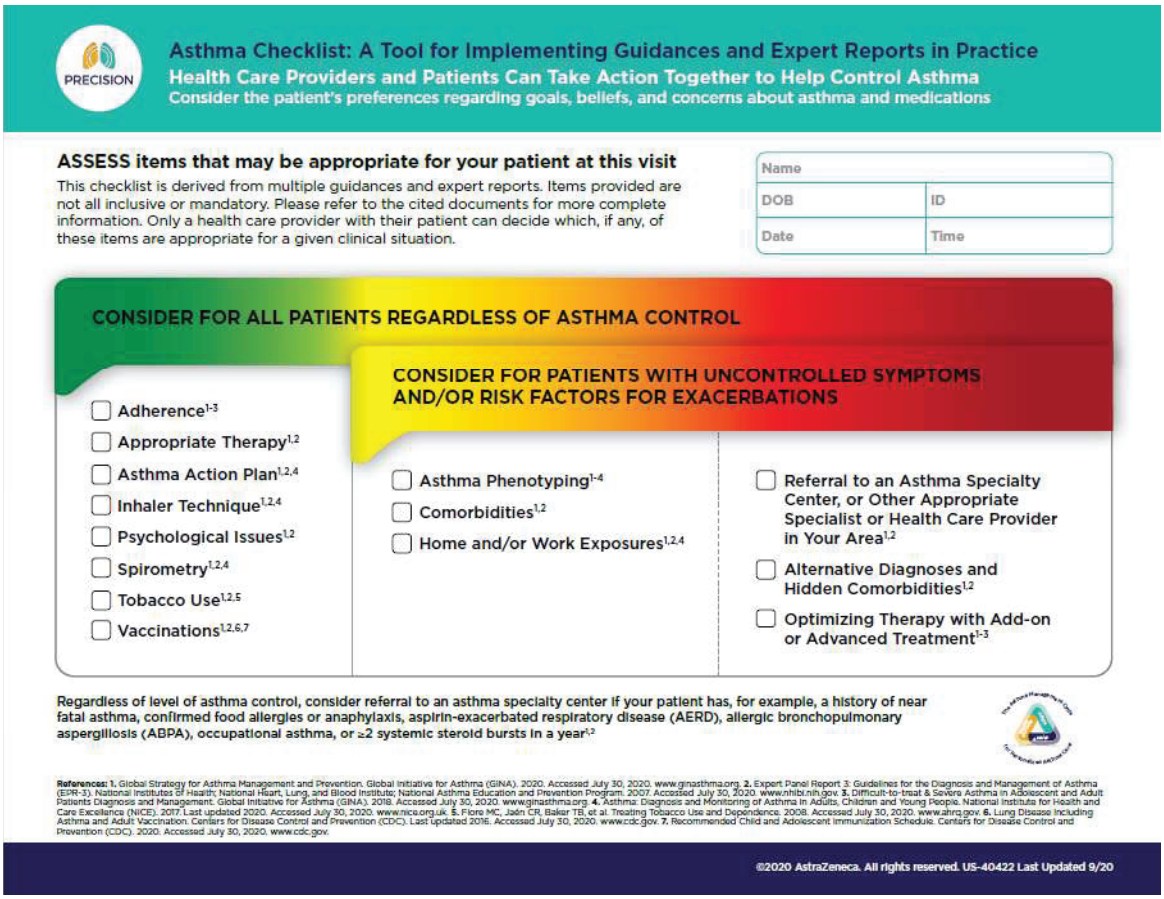





PRECISION
HOME
ABOUT PRECISION
ASTHMA CHECKLIST
PROVIDER RESOURCES
PATIENT EDUCATION
PATIENT ANIMATIONS
response to selected ADJUST items.
Guidances and Expert Reports
Asthma Checklist: A Tool for Implementing Guidances and Expert Reports in Practice and ASSESS, ADJUST, AND REVIEW RESPONSE are based on key US and other guidances and expert reports including:
Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma (GINA). 2020. Accessed November 24, 2020. https://ginasthma.org/wp-content/uploads/2020/04/GINA-2020-full-report_-final-_wms.pdf.
Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). National Institutes of Health; National Heart, Lung, and Blood Institute; National Asthma Education and Prevention Program. 2007. Accessed November 24, 2020. https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthsumm.pdf.
Difficult-to-treat & Severe Asthma in Adolescent and Adult Patients Diagnosis and Management. Global Initiative for Asthma (GINA). 2019. Accessed November 24, 2020. https://ginasthma.org/wp-content/uploads/2019/04/GINA-Severe-asthma-Pocket-Guide-v2.0-wms-1.pdf.
Asthma: Diagnosis and Monitoring of Asthma in Adults, Children and Young People. National Institute for Health and Care Excellence (NICE). 2017. Updated 2020. Accessed November 24, 2020. https://www.nice.org.uk/guidance/ng80/resources/asthma-diagnosis-monitoring-and-chronic-asthma-management-pdf-1837687975621.
Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Accessed November 24, 2020. https://www.ncbi.nlm.nih.gov/books/NBK63952/.
Lung Disease Including Asthma and Adult Vaccination. Centers for Disease Control and Prevention (CDC). Updated 2016. Accessed November 24, 2020. https://www.cdc.gov/vaccines/adults/rec-vac/health-conditions/lung-disease.html.
Recommended Child and Adolescent Immunization Schedule. Centers for Disease Control and Prevention (CDC). 2020. Accessed November 24, 2020. https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.
Expert Panel Report 4 (EPR-4) Working Group, National Institutes of Health; National Heart,
Go to Asthma Checklist
Click the button to open and download the Asthma Checklist

Asthma Checklist

Page 1: Assess



PRECISION

Asthma Checklist: A Tool for Implementing Guidances and Expert Reports in Practice
Health Care Providers and Patients Can Take Action Together to Help Control Asthma
Consider the patient's preferences regarding goals, beliefs, and concerns about asthma and medications

ASSESS items that may be appropriate for your patient at this visit

This checklist is derived from multiple guidances and expert reports. Items provided are not all inclusive or mandatory. Please refer to the cited documents for more complete information. Only a health care provider with their patient can decide which, if any, of these items are appropriate for a given clinical situation.

Name	
DOB	ID
Date	Time

CONSIDER FOR ALL PATIENTS REGARDLESS OF ASTHMA CONTROL

- ☐ Adherence[1-3]
- ☐ Appropriate Therapy[1,2]
- ☐ Asthma Action Plan[1,2,4]
- ☐ Inhaler Technique[1,2,4]
- ☐ Psychological Issues[1,2]
- ☐ Spirometry[1,2,4]
- ☐ Tobacco Use[1,2,5]
- ☐ Vaccinations[1,2,6,7]

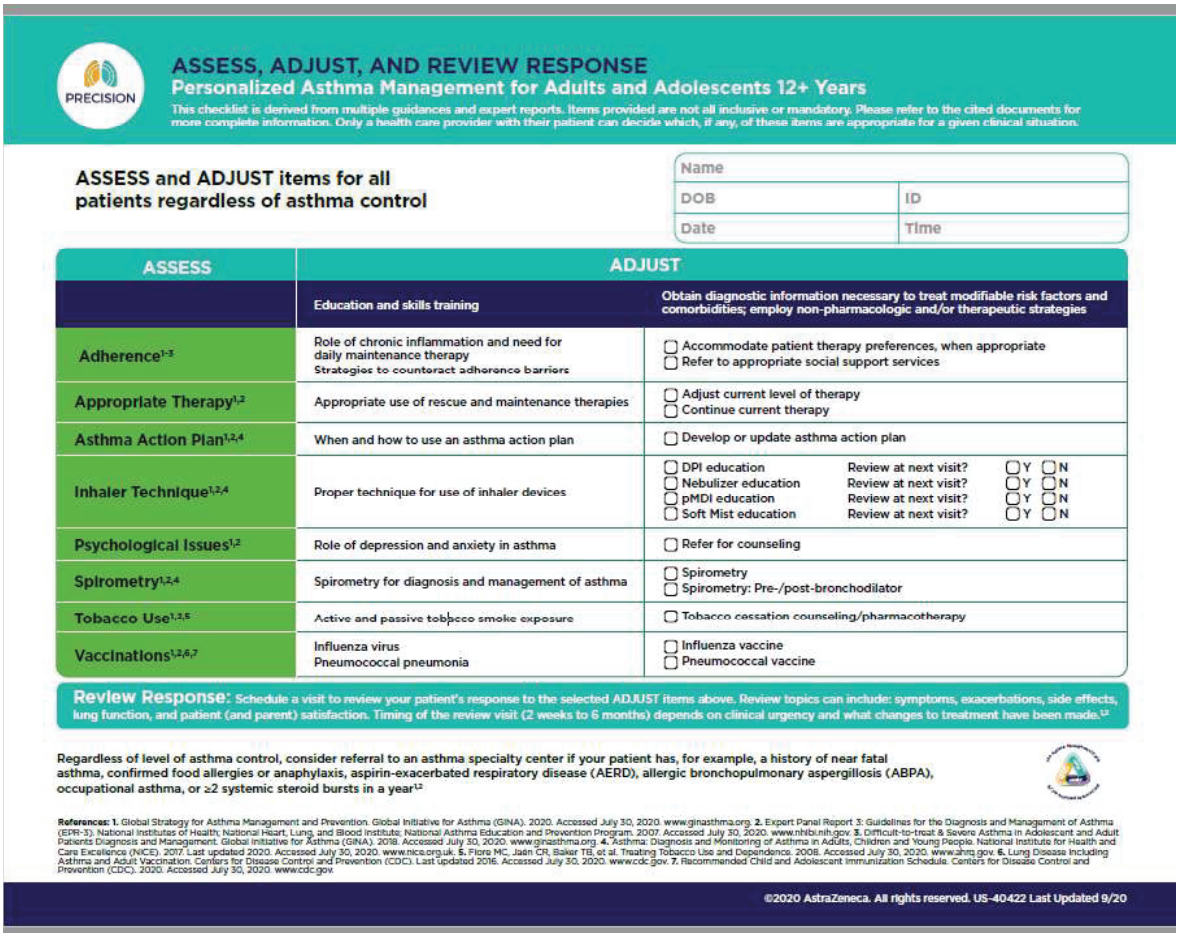
CONSIDER FOR PATIENTS WITH UNCONTROLLED SYMPTOMS AND/OR RISK FACTORS FOR EXACERBATIONS

- ☐ Asthma Phenotyping[1-4]
- ☐ Comorbidities[1,2]
- ☐ Home and/or Work Exposures[1,2,4]
- ☐ Referral to an Asthma Specialty Center, or Other Appropriate Specialist or Health Care Provider in Your Area[1,2]
- ☐ Alternative Diagnoses and Hidden Comorbidities[1,2]
- ☐ Optimizing Therapy with Add-on or Advanced Treatment[1-3]

Regardless of level of asthma control, consider referral to an asthma specialty center if your patient has, for example, a history of near fatal asthma, confirmed food allergies or anaphylaxis, aspirin-exacerbated respiratory disease (AERD), allergic bronchopulmonary aspergillosis (ABPA), occupational asthma, or ≥2 systemic steroid bursts in a year[1,2]

References: 1. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma (GINA). 2020. Accessed July 30, 2020. www.ginasthma.org. 2. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). National Institutes of Health; National Heart, Lung, and Blood Institute; National Asthma Education and Prevention Program. 2007. Accessed July 30, 2020. www.nhlbi.nih.gov. 3. Difficult-to-treat & Severe Asthma in Adolescent and Adult Patients Diagnosis and Management. Global Initiative for Asthma (GINA). 2018. Accessed July 30, 2020. www.ginasthma.org. 4. Asthma: Diagnosis and Monitoring of Asthma in Adults, Children and Young People. National Institute for Health and Care Excellence (NICE). 2017. Last updated 2020. Accessed July 30, 2020. www.nice.org.uk. 5. Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008. Accessed July 30, 2020. www.ahrq.gov. 6. Lung Disease including Asthma and Adult Vaccination. Centers for Disease Control and Prevention (CDC). Last Updated 2016. Accessed July 30, 2020. www.cdc.gov. 7. Recommended Child and Adolescent Immunization Schedule. Centers for Disease Control and Prevention (CDC). 2020. Accessed July 30, 2020. www.cdc.gov.

Page 2. Adjust



PRECISION

ASSESS, ADJUST, AND REVIEW RESPONSE
Personalized Asthma Management for Adults and Adolescents 12+ Years

This checklist is derived from multiple guidances and expert reports. Items provided are not all inclusive or mandatory. Please refer to the cited documents for more complete information. Only a health care provider with their patient can decide which, if any, of these items are appropriate for a given clinical situation.

ASSESS and ADJUST items for all patients regardless of asthma control

Name	
DOB	ID
Date	Time

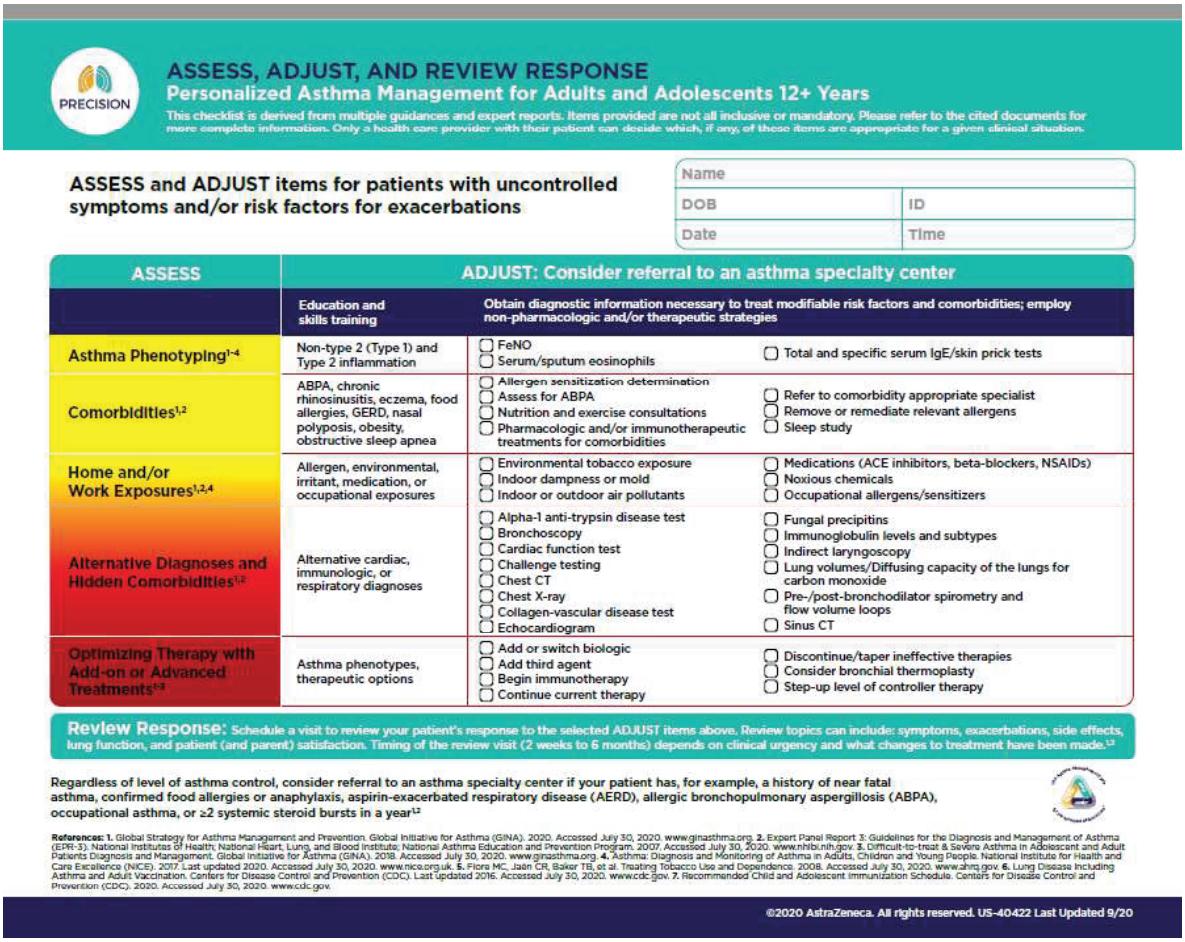
ASSESS	ADJUST	
	Education and skills training	Obtain diagnostic information necessary to treat modifiable risk factors and comorbidities; employ non-pharmacologic and/or therapeutic strategies
Adherence[1-3]	Role of chronic inflammation and need for daily maintenance therapy Strategies to counteract adherence barriers	☐ Accommodate patient therapy preferences, when appropriate ☐ Refer to appropriate social support services
Appropriate Therapy[1,2]	Appropriate use of rescue and maintenance therapies	☐ Adjust current level of therapy ☐ Continue current therapy
Asthma Action Plan[1,2,4]	When and how to use an asthma action plan	☐ Develop or update asthma action plan
Inhaler Technique[1,2,4]	Proper technique for use of inhaler devices	☐ DPI education Review at next visit? ☐ Y ☐ N ☐ Nebulizer education Review at next visit? ☐ Y ☐ N ☐ pMDI education Review at next visit? ☐ Y ☐ N ☐ Soft Mist education Review at next visit? ☐ Y ☐ N
Psychological Issues[1,2]	Role of depression and anxiety in asthma	☐ Refer for counseling
Spirometry[1,2,4]	Spirometry for diagnosis and management of asthma	☐ Spirometry ☐ Spirometry: Pre-/post-bronchodilator
Tobacco Use[1,2,5]	Active and passive tobacco smoke exposure	☐ Tobacco cessation counseling/pharmacotherapy
Vaccinations[1,2,6,7]	Influenza virus Pneumococcal pneumonia	☐ Influenza vaccine ☐ Pneumococcal vaccine

Review Response: Schedule a visit to review your patient's response to the selected ADJUST items above. Review topics can include: symptoms, exacerbations, side effects, lung function, and patient (and parent) satisfaction. Timing of the review visit (2 weeks to 6 months) depends on clinical urgency and what changes to treatment have been made.[1,2]

Regardless of level of asthma control, consider referral to an asthma specialty center if your patient has, for example, a history of near fatal asthma, confirmed food allergies or anaphylaxis, aspirin-exacerbated respiratory disease (AERD), allergic bronchopulmonary aspergillosis (ABPA), occupational asthma, or ≥2 systemic steroid bursts in a year[1,2]

References: 1. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma (GINA). 2020. Accessed July 30, 2020. www.ginasthma.org. **2.** Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). National Institutes of Health; National Heart, Lung, and Blood Institute; National Asthma Education and Prevention Program. 2007. Accessed July 30, 2020. www.nhlbi.nih.gov. **3.** Difficult-to-treat & Severe Asthma in Adolescent and Adult Patients Diagnosis and Management. Global Initiative for Asthma (GINA). 2018. Accessed July 30, 2020. www.ginasthma.org. **4.** Asthma: Diagnosis and Monitoring of Asthma in Adults, Children and Young People. National Institute for Health and Care Excellence (NICE). 2017. Last updated 2020. Accessed July 30, 2020. www.nice.org.uk. **5.** Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence. 2008. Accessed July 30, 2020. www.ahrq.gov. **6.** Lung Disease Including Asthma and Adult Vaccination. Centers for Disease Control and Prevention (CDC). Last updated 2016. Accessed July 30, 2020. www.cdc.gov. **7.** Recommended Child and Adolescent Immunization Schedule. Centers for Disease Control and Prevention (CDC). 2020. Accessed July 30, 2020. www.cdc.gov.

Page 3. Review Response



PRECISION

ASSESS, ADJUST, AND REVIEW RESPONSE
Personalized Asthma Management for Adults and Adolescents 12+ Years

This checklist is derived from multiple guidances and expert reports. Items provided are not all inclusive or mandatory. Please refer to the cited documents for more complete information. Only a health care provider with their patient can decide which, if any, of these items are appropriate for a given clinical situation.

ASSESS and ADJUST items for patients with uncontrolled symptoms and/or risk factors for exacerbations

Name	
DOB	ID
Date	Time

ASSESS	ADJUST: Consider referral to an asthma specialty center		
	Education and skills training	Obtain diagnostic information necessary to treat modifiable risk factors and comorbidities; employ non-pharmacologic and/or therapeutic strategies	
Asthma Phenotyping[1-4]	Non-type 2 (Type 1) and Type 2 inflammation	☐ FeNO ☐ Serum/sputum eosinophils	☐ Total and specific serum IgE/skin prick tests
Comorbidities[1,2]	ABPA, chronic rhinosinusitis, eczema, food allergies, GERD, nasal polyposis, obesity, obstructive sleep apnea	☐ Allergen sensitization determination ☐ Assess for ABPA ☐ Nutrition and exercise consultations ☐ Pharmacologic and/or immunotherapeutic treatments for comorbidities	☐ Refer to comorbidity appropriate specialist ☐ Remove or remediate relevant allergens ☐ Sleep study
Home and/or Work Exposures[1,2,4]	Allergen, environmental, irritant, medication, or occupational exposures	☐ Environmental tobacco exposure ☐ Indoor dampness or mold ☐ Indoor or outdoor air pollutants	☐ Medications (ACE inhibitors, beta-blockers, NSAIDs) ☐ Noxious chemicals ☐ Occupational allergens/sensitizers
Alternative Diagnoses and Hidden Comorbidities[1,2]	Alternative cardiac, immunologic, or respiratory diagnoses	☐ Alpha-1 anti-trypsin disease test ☐ Bronchoscopy ☐ Cardiac function test ☐ Challenge testing ☐ Chest CT ☐ Chest X-ray ☐ Collagen-vascular disease test ☐ Echocardiogram	☐ Fungal precipitins ☐ Immunoglobulin levels and subtypes ☐ Indirect laryngoscopy ☐ Lung volumes/Diffusing capacity of the lungs for carbon monoxide ☐ Pre-/post-bronchodilator spirometry and flow volume loops ☐ Sinus CT
Optimizing Therapy with Add-on or Advanced Treatments[5-9]	Asthma phenotypes, therapeutic options	☐ Add or switch biologic ☐ Add third agent ☐ Begin immunotherapy ☐ Continue current therapy	☐ Discontinue/taper ineffective therapies ☐ Consider bronchial thermoplasty ☐ Step-up level of controller therapy

Review Response: Schedule a visit to review your patient's response to the selected ADJUST items above. Review topics can include: symptoms, exacerbations, side effects, lung function, and patient (and parent) satisfaction. Timing of the review visit (2 weeks to 6 months) depends on clinical urgency and what changes to treatment have been made.[1,3]

Regardless of level of asthma control, consider referral to an asthma specialty center if your patient has, for example, a history of near fatal asthma, confirmed food allergies or anaphylaxis, aspirin-exacerbated respiratory disease (AERD), allergic bronchopulmonary aspergillosis (ABPA), occupational asthma, or ≥2 systemic steroid bursts in a year[1,2]

References: 1. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma (GINA). 2020. Accessed July 30, 2020. www.ginasthma.org. **2.** Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). National Institutes of Health; National Heart, Lung, and Blood Institute; National Asthma Education and Prevention Program. 2007. Accessed July 30, 2020. www.nhlbi.nih.gov. **3.** Difficult-to-treat & Severe Asthma in Adolescent and Adult Patients Diagnosis and Management. Global Initiative for Asthma (GINA). 2018. Accessed July 30, 2020. www.ginasthma.org. **4.** Asthma: Diagnosis and Monitoring of Asthma in Adults, Children and Young People. National Institute for Health and Care Excellence (NICE). 2017. Last updated 2020. Accessed July 30, 2020. www.nice.org.uk. **5.** Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence. 2008. Accessed July 30, 2020. www.ahrq.gov. **6.** Lung Disease Including Asthma and Adult Vaccination. Centers for Disease Control and Prevention (CDC). Last updated 2016. Accessed July 30, 2020. www.cdc.gov. **7.** Recommended Child and Adolescent Immunization Schedule. Centers for Disease Control and Prevention (CDC). 2020. Accessed July 30, 2020. www.cdc.gov.

Quick Reference for Point Care Use

Selections from the US Guidelines and Global Report on Asthma

Appendix K_US Guidelines and Global

Using an Asthma Action Plan

Appendix K_Using an Ashma Action Plan.pd

Appendix K_Using an Ashma Action Plan.pd

Appendix K_Using an Ashma Action Plan.pd

In-Depth Information for Self-directed Review

Asthma Phenotypes and Endotypes

Appendix K_Asthma phenotypes and en

Appendix K_Asthma phenotypes and en

Appendix K_Asthma phenotypes and enc

Diagnosing Comorbidities Associated with Asthma

Appendix K_Diagnosing como

Appendix K_Diagnosing como

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Inhaler Selection and Technique Training

Appendix K_Inhaler selecting and techni

Appendix K_Inhaler selecting and techni

Appendix K_Inhaler selecting and techni

Systematic Approach to Spirometry

Appendix K_Systematic approa

APPENDIX L. ASTHMA CLINIC EXPERIENCE (ACE) QUESTIONNAIRE (ENGLISH VERSION)

PRECISION

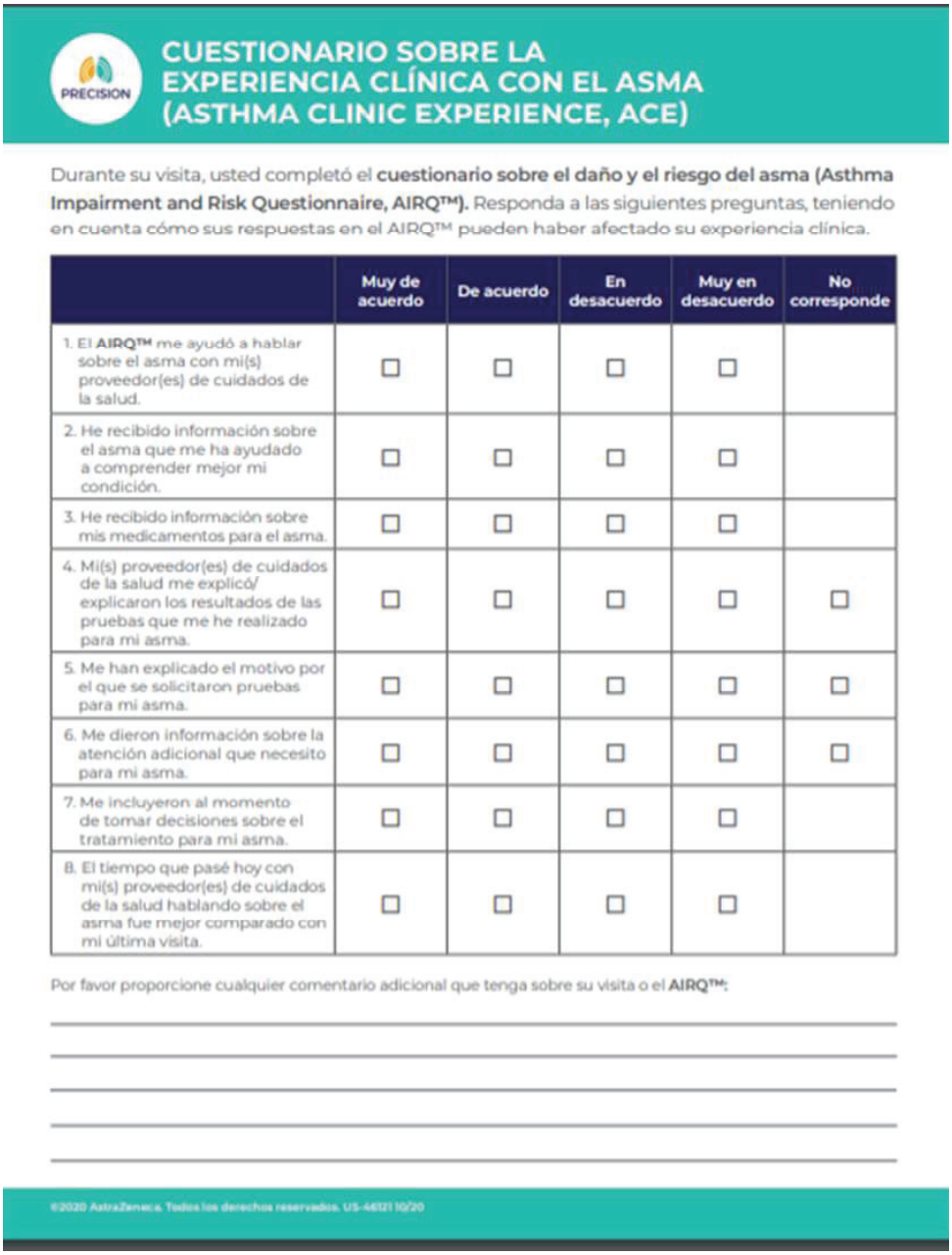
ASTHMA CLINIC EXPERIENCE (ACE) QUESTIONNAIRE

During your visit, you filled out the **Asthma Impairment and Risk Questionnaire (AIRQ™).** Please answer the following questions, keeping in mind how your answers to the AIRQ™ may have affected your clinic experience.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Not Applicable
1. The **AIRQ™** helped me discuss my asthma with my health care provider(s).	☐	☐	☐	☐	
2. I received information about my asthma that helped me better understand my condition.	☐	☐	☐	☐	
3. I received information about my asthma medications.	☐	☐	☐	☐	
4. My health care provider(s) explained the results of tests that I have taken for my asthma.	☐	☐	☐	☐	☐
5. I was told the reason why tests for my asthma were ordered.	☐	☐	☐	☐	☐
6. I was given information about additional care that I need for my asthma.	☐	☐	☐	☐	☐
7. I was included in making decisions about my asthma treatment.	☐	☐	☐	☐	
8. The time spent with my health care provider(s) today discussing my asthma was better compared to my last visit.	☐	☐	☐	☐	

Please provide any additional comments you have about your visit or **AIRQ™:**

APPENDIX M. ASTHMA CLINIC EXPERIENCE QUESTIONNAIRE (SPANISH VERSION)



PRECISION

CUESTIONARIO SOBRE LA EXPERIENCIA CLÍNICA CON EL ASMA (ASTHMA CLINIC EXPERIENCE, ACE)

Durante su visita, usted completó el **cuestionario sobre el daño y el riesgo del asma (Asthma Impairment and Risk Questionnaire, AIRQ™).** Responda a las siguientes preguntas, teniendo en cuenta cómo sus respuestas en el AIRQ™ pueden haber afectado su experiencia clínica.

	Muy de acuerdo	De acuerdo	En desacuerdo	Muy en desacuerdo	No corresponde
1. El **AIRQ™** me ayudó a hablar sobre el asma con mi(s) proveedor(es) de cuidados de la salud.	☐	☐	☐	☐	
2. He recibido información sobre el asma que me ha ayudado a comprender mejor mi condición.	☐	☐	☐	☐	
3. He recibido información sobre mis medicamentos para el asma.	☐	☐	☐	☐	
4. Mi(s) proveedor(es) de cuidados de la salud me explicó/ explicaron los resultados de las pruebas que me he realizado para mi asma.	☐	☐	☐	☐	☐
5. Me han explicado el motivo por el que se solicitaron pruebas para mi asma.	☐	☐	☐	☐	☐
6. Me dieron información sobre la atención adicional que necesito para mi asma.	☐	☐	☐	☐	☐
7. Me incluyeron al momento de tomar decisiones sobre el tratamiento para mi asma.	☐	☐	☐	☐	
8. El tiempo que pasé hoy con mi(s) proveedor(es) de cuidados de la salud hablando sobre el asma fue mejor comparado con mi última visita.	☐	☐	☐	☐	

Por favor proporcione cualquier comentario adicional que tenga sobre su visita o el **AIRQ™:**


CCI


CCI


CCI

CCI

Placeholder

APPENDIX R. PATIENT SOCIODEMOGRAPHICS QUESTIONNAIRE (ENGLISH VERSION)

Please complete all questions, if possible.

1. *What is your age? _____ years*

2. *What is your sex?*

   ☐ male ☐ female ☐ non-binary ☐ Other:_____

3. *What is your ethnic background?*

   ☐ Hispanic or Latino
   ☐ Not Hispanic or Latino

4. *What is your racial background? (Please mark all boxes that apply with an "X.")*

   ☐ White
   ☐ Black or African American
   ☐ Asian
   ☐ Native Hawaiian or other Pacific Islander
   ☐ American Indian or Alaska Native
   ☐ Other (specify): _____

5. *What is your current living/domestic situation? (Please mark only one box with an "X.")*

   ☐ Living alone
   ☐ Living with a spouse, partner, family, or friends
   ☐ Other (specify): _____

6. *How would you describe your employment status? (Please mark only one box with an "X.")*

   ☐ Employed, full-time
   ☐ Employed, part-time
   ☐ Homemaker
   ☐ Student
   ☐ Unemployed
   ☐ Retired
   ☐ Disabled
   ☐ Other (specify): _____

7. *What is the highest level of education you have completed? (Please mark only one box with an "X.")*

   ☐ Less than high school
   ☐ Secondary/high school
   ☐ Associate degree, technical or trade school
   ☐ College/university degree
   ☐ Postgraduate school
   ☐ Other (specify): _____

8. What is your household's total income from all sources over the past 12 months?

   ☐ Less than $15,000
   ☐ $15,000 to $29,999
   ☐ $30,000 to $44,999
   ☐ $45,000 to $59,999
   ☐ $60,00 to $74,999
   ☐ $75,000 to $99,999
   ☐ $100,000 or more
   ☐ Prefer not to answer

9. *How old were you when you were diagnosed with asthma?* _____

10. *Do you smoke?*

    ☐ Yes, current smoker
    ☐ Not currently, but previous smoker
    ☐ No, never smoked

APPENDIX S. PATIENT SOCIODEMOGRAPHICS QUESTIONNAIRE (SPANISH VERSION)

Placeholder

APPENDIX T. CLINICAL SITE TOUCH POINT QUESTIONS

1. Please describe how the PRECISION Program is being implemented at your site?

2. What aspects of study implementation are going well for your site? Telehealth vs in-person?

3. What aspects of study implementation have been challenging for your site? Has the site experienced any barriers to implementing the PRECISION program? Telehealth vs in-person?

4. Please describe any site-level factors (e.g., site operations, clinical team) that have affected the implementation of the PRECISION Program on a telehealth platform at your site? During an in-person visit?

5. What could be done to help overcome these site-level challenges and support the use of the PRECISION Program on a telehealth platform at your site? During an in-person visit?

6. Please describe any participant-level factors that have affected the implementation of the PRECISION Program on a telehealth platform at your site? During an in-person visit?

7. Based on your experiences to date, does your site plan to make any changes or adapt how the PRECISION Program is currently being implemented on a telehealth platform at your site? During an in-person visit?

APPENDIX U. POST-STUDY SURVEY

PART 1. INFORMED CONSENT

PART 2. POST-STUDY SURVEY

1. Approximately how many patients have you treated using the PRECISION Program?

   _____

2. Which visit type best describes how the majority of your initial patient visits took place?

   ☐ Telehealth visit (approximately __ %)
   ☐ In-person visit (approximately __ %)

3. How would you rate the overall ease of implementing the AIRQ™ into your clinical practice using the telehealth platform?

   ☐ Very easy
   ☐ Somewhat easy
   ☐ Difficult
   ☐ Very Difficult

4. How would you rate the overall ease of implementing the AIRQ™ into your clinical practice during an in-person visit?

   ☐ Very easy
   ☐ Somewhat easy
   ☐ Difficult
   ☐ Very Difficult

5. Did the AIRQ™ help you manage your patients?

   ☐ Yes, very much
   ☐ Yes, somewhat
   ☐ Not at all

6. Regardless of intermittent or persistent, on average, what percentage of your asthma patients would you classify as:

   ___ % Mild asthma
   ___% Moderate asthma
   ___% Severe asthma
   = 100%

7. Did AIRQ™ help you identify patients who were at risk for adverse health outcomes (e.g., hospitalizations, exacerbations, medication side effects) from their asthma that you would have otherwise missed?

   ☐ Yes
   ☐ No

8. What did you find most useful about AIRQ™?

   ☐ Total AIRQ™ score
   ☐ Questions on impact/impairment (#1-6)
   ☐ Question on control (#7)
   ☐ Questions on exacerbations and healthcare resource utilization (#8-10)

9. What did you find least useful or cumbersome about AIRQ™?

   ☐ Total AIRQ™ score
   ☐ Questions on impact/impairment (#1-6)
   ☐ Question on control (#7)
   ☐ Questions on exacerbations and healthcare resource utilization (#8-10)

10. Did AIRQ™ improve any of the following: *Check all that apply*

    ☐ Increased recognition of patients whose asthma placed their health at risk
    ☐ Increased recognition of conditions/risks, comorbidities driving poor asthma control
    ☐ Improved recognition of patient goals
    ☐ Improved patient engagement with their treatment, risk, or control
    ☐ Improved efficiency of patient telehealth visit
    ☐ Improved efficiency of in-person asthma clinic visit
    ☐ Increased educational efforts

11. While using AIRQ™, how often did you refer to a specialist or practice type different than your own?
    ☐ No different than if I did not have the tools
    ☐ More often than before
    ☐ Less often than before

12. What features of the PRECISION program did you find most useful?

    _____

    _____

    _____

13. What features of the PRECISION program do you think could be improved?

_____

_____

_____

14. How important was it for you to use the Assess component of the Asthma Checklist (page 1) with the AIRQ?

☐ Very important
☐ Somewhat important
☐ Not at all important
☐ Did not use

15. How important was it for you to use the Adjust and Review components of the Asthma Checklist (pages 2 and 3)?

☐ Very important
☐ Somewhat important
☐ Not at all important
☐ Did not use

16. How important do you feel it would be for PCPs to use the Assess component of the Asthma Checklist (page 1) with the AIRQ?

☐ Very important
☐ Somewhat important
☐ Not at all important
☐ Did not use

17. How important do you feel it would be for Specialists to use the Adjust/Review pages of the Asthma Checklist with the AIRQ?

☐ Very important
☐ Somewhat important
☐ Not at all important
☐ Did not use

18. How important do you feel it would be for Non-prescribers to use the Assess component of the Asthma Checklist (page 1) with the AIRQ?

☐ Very important
☐ Somewhat important
☐ Not at all important
☐ Did not use

19. Do you have any other comments or suggestions?

_____

_____

_____

APPENDIX V. SEMI-STRUCTURED INTERVIEW GUIDES

INTERVIEW GUIDE: KEY CLINICAL SITE STAFF

Interviewer: *Before you meet with the participant for the interview, be sure to look over answers from the Post-study Survey and the site's responses from the Site Feasibility Questionnaire about whether the site has indicated any specific initiative to achieve with the AIRQ™ or what made the site unique for participating in this study.*

Part 1. Before the interview begins, be sure to document verbal consent using the script below

Part 2. Below is the discussion guide, it is to be used as a guide only. The actual areas of conversation are fluid and may be discussed at moments different from the order appearing below.

PART 1. KEY CLINICAL SITE STAFF INFORMED VERBAL CONSENT SCRIPT

PART 2. INTERVIEW

INTERVIEW RULES FOR ALL INTERVIEWS

Please feel free to answer honestly. We are interested in your feedback and observations from implementing these tools in your clinical practice over the past several months.

Turn on Recorder and Begin Interview: This is [***interviewee's name***] with participant [***participant ID***] for Study **EVA-26645-04** on [***Date***]. I want to confirm that you agree to participate in this interview and that you agree to today's interview being audio recorded. **Is that correct?**

____

Background

First, I would like to ask you some background questions.

1. What are your key responsibilities at the clinic?
2. What were your key responsibilities for this implementation study?
3. In general, how did your site conduct the patient visit? *Probe: by telehealth platform, by in-person clinic visit.?*
4. In general, how did your site conduct the telehealth visits? *Probe: by telephone, computer, tablet, etc.?*

Now I would like to ask you some questions about the process you used to administer the AIRQ™, the Asthma Checklist, and educational resources (PRECISION program) as part of a patient's telehealth visit for this study.

Process for Telehealth visit with AIRQ™

5. In your own words, how would you describe the process you used to administer the AIRQ™ to patients during a telehealth visit? (*listen for who administered AIRQ™ and how it was administered and process (i.e., as part of initial intake, by HCP, etc.)*
6. Approximately how long did it take patients to complete just AIRQ™ during a telehealth visit?
7. Did patients have any problems completing the AIRQ™ as part of the telehealth visit?
   a. Did they ask you questions about specific items included in the AIRQ™? If so, what type of questions did they generally ask?
8. What was the process you use to provide the AIRQ™ results to the HCP?

Process for In-Person visit with AIRQ™

9. In your own words, how would you describe the process you used to administer the AIRQ™ to patients during an in-person visit? (*listen for who administered AIRQ™ and how it was administered and process (i.e., as part of initial intake, by HCP, etc.)*
10. Approximately how long did it take patients to complete just AIRQ™ during an in-person visit?
11. Did patients have any problems completing the AIRQ™ as part of the in-person visit?
12. Did any of your patients use the Spanish version of the AIRQ™? If so, how did you administer the Spanish version? Were there any difficulties using the Spanish version? Going back and forth between English and Spanish versions?
13. What was the process you use to provide the AIRQ™ results to the HCP?

Asthma Checklist and Educational Resources

14. Did you use the full Asthma Checklist and education resources from the study website? If so,
    a. In what capacity did you use this information? (telehealth vs in-person)
    b. What did you find most useful about this information?
    c. What did you find least useful about this information?

Entire Program

15. Thinking about the entire PRECISION program, how much extra time at each patient telehealth visit did it take to incorporate the AIRQ™ as part of the telehealth visit? What about in-person visits?
16. Were there any specific steps or initiatives taken at your clinical site to implement the AIRQ™ for telehealth? Please explain.
17. What were some of the initial challenges of incorporating the PRECISION tools into your daily clinical practice? *Probe: implementing AIRQ™ on the telehealth platform and incorporating AIRQ™ to the regular in-person telehealth visit?*
18. How were you able to overcome these challenges?
19. What challenges remained throughout the study?
20. How can we address these challenges during future site trainings?
21. Which aspects of the PRECISION program are you most likely to continue using, and why? Which ones had the least value to your clinical practice/

Overall Comments

22. What did you think of the overall PRECISION program?
23. What do you think needs to be done to support the continued use of the PRECISION program at your clinical site?
24. Do you have any other comments or suggestions?

INTERVIEW GUIDE: CLINICIAN

Interviewer: *Before you meet with the participant for the interview, be sure to look over answers from the Post-study Survey and the site's responses from the Site Feasibility Questionnaire about whether the site has indicated any specific initiative to achieve with the AIRQ™ or what made the site unique for participating in this study.*

Part 1. Before the interview begins, be sure to document verbal consent using the script below

Part 2. Below is the discussion guide, it is to be used as a guide only. The actual areas of conversation are fluid and may be discussed at moments different from the order appearing below.

PART 1. CLINICIAN INFORMED VERBAL CONSENT SCRIPT

PART 2. INTERVIEW

INTERVIEW RULES FOR ALL INTERVIEWS

Please feel free to answer honestly. We are interested in your feedback and observations from implementing these tools in your clinical practice over the past several months.

Turn on Recorder and Begin Interview: This is [***interviewee's name***] with participant [***participant ID***] for Study **EVA-26645-04** on [***Date***]. I want to confirm that you agree to participate in this interview and that you agree to today's interview being audio recorded. **Is that correct?**

____

Background

1. What are your overall thoughts on the AIRQ™, the Asthma Checklist, and educational resources (PRECISION program)? *Probe: Assess component, Review/Adjust component of Asthma checklist*
2. How useful was the AIRQ™ when used during a telehealth visit? *Probe: identify patients at risk, guide treatment, and asthma work-up and management?*
3. How useful was the AIRQ™ when used during an in-person visit? *Probe: identify patients at risk, guide treatment, and asthma work-up and management?*
4. Were there specific questions on the AIRQ™ that you thought were the most useful? The least useful?
5. How useful were the Asthma Checklist and other educational resources as part of the telehealth platform? In-person visit?
6. What did you like about the PRECISION program?
7. What did you not like about the PRECISION program?

Interviewer: Remind *the clinician of any specific initiative they thought they could achieve with the AIRQ™, the Asthma Checklist, and educational resources (PRECISION program) or what made them unique for participating in this study before the interview.*

1. When you started this study, you had indicated [specific QI initiatives/uniqueness of site]. Can you speak to this a bit? How has AIRQ™, the Asthma Checklist, and education resources (PRECISION program) been incorporated into this initiative? How has it helped? What were some of the challenges/benefits?
2. Will your site continue to incorporate the AIRQ™, Asthma Checklist, and educational resources (PRECISION program) when the study is over? Why or why not?
3. What do you think needs to be done to support the continued use of the PRECISION program in your clinical practice?

Do you have any other comments or suggestions?


CCI

APPENDIX X. ADVERTISEMENT

APPENDIX Y. RECRUITMENT TRACKING LOG

RECRUITMENT TRACKING LOG (EVA-26645-03): SITE [XXX]

Please send the Recruitment Tracking Log to Evidera every Wednesday (studyemail@evidera.com)

Screen Date	Patient Age	Patient Gender	Outcome	Verbal Consent obtained	If ineligible, record criteria	Date and time of visit; Participant ID	Type of Visit
02/15/21	PPD	PPD	PPD	Yes 02/15/2021		PPD	☒ Telehealth ❑ In-person
02/15/21	PPD	PPD	PPD	N/a	PPD		❑ Telehealth ❑ In-person
		❑ Male ❑ Female	❑ Eligible ❑ Ineligible ❑ Declined				☒ Telehealth ❑ In-person
		❑ Male ❑ Female	❑ Eligible ❑ Ineligible ❑ Declined				☒ Telehealth ❑ In-person

APPENDIX Z. E-MAIL FOR POST VISIT PATIENT SURVEY (ENGLISH VERSION)

APPENDIX AA. E-MAIL FOR POST VISIT PATIENT SURVEY (SPANISH VERSION)

Placeholder

APPENDIX BB. REMINDER E-MAILS FOR POST VISIT PATIENT SURVEY (ENGLISH VERSION)

APPENDIX CC. REMINDER E-MAILS FOR POST VISIT PATIENT SURVEY (SPANISH VERSION)

Placeholder

APPENDIX DD. DESCRIPTION OF DRUGS IN EACH DRUG CLASS

MAINTENANCE PHARMACOLOGIC THERAPY

ICS

- ☐ QVAR HFA 40 mcg (Beclomethasone)
- ☐ Beclovent HFA 40 mcg (Beclomethasone)
- ☐ Vanceril HFA 42 mcg (Beclomethasone)
- ☐ QVAR HFA 80 mcg (Beclomethasone)
- ☐ Beclovent HFA 80 mcg (Beclomethasone)
- ☐ Vanceril HFA 84 mcg (Beclomethasone)
- ☐ QVAR Redihaler 40 mcg (Beclomethasone)
- ☐ QVAR Redihaler 80 mcg (Beclomethasone)
- ☐ Pulmicort Flexhaler 90 mcg (Budesonide)
- ☐ Pulmicort Flexhaler 180 mcg (Budesonide)
- ☐ Pulmicort Respules 0.25 mg (Budesonide)
- ☐ Pulmicort Respules 0.5 mg (Budesonide)
- ☐ Pulmicort Respules 1 mg (Budesonide)
- ☐ Aerospan HFA 80 mcg (Flunisolide)
- ☐ Flunisolide
- ☐ Flovent HFA 44 mcg (Fluticasone Propionate)
- ☐ Flovent HFA 110 mcg (Fluticasone Propionate)
- ☐ Flovent HFA 220 mcg (Fluticasone Propionate)
- ☐ Flovent Disc 50 mcg (Fluticasone Propionate)
- ☐ Flovent Disc 100 mcg (Fluticasone Propionate)
- ☐ Flovent Disc 250 mcg (Fluticasone Propionate)
- ☐ Azmanex Twisthaler 110 mcg (Mometasone)
- ☐ Azmanex Twisthaler 220 mcg (Mometasone)
- ☐ Azmanex HFA 100 mcg (Mometasone)
- ☐ Azmanex HFA 220 mcg (Mometasone)
- ☐ Arnuity Ellipta 100 mcg (Fluticasone Furoate)
- ☐ Arnuity Ellipta 200 mcg (Fluticasone Furoate)
- ☐ Triamcinolbone Acetonide
- ☐ Alvesco 80 mcg (Ciclesonide)
- ☐ Alvesco 160 mcg (Ciclesonide)
- ☐ Other (specify): _____
- ☐ Other (specify): _____

ICS/LABA

- ☐ Advair Diskus 100/50 (Fluticasone/Salmeterol)
- ☐ Advair Diskus 250/50 (Fluticasone/Salmeterol)
- ☐ Advair Diskus 500/50 (Fluticasone/Salmeterol)
- ☐ Advair HFA 45/21 (Fluticasone/Salmeterol)

LABA (Single inhaled medicine, *not* in a fixed-dose combination with an ICS or ICS/LAMA)

- ☐ Serevent/ Salmeterol
- ☐ Foradil/Formoterol
- ☐ Arcapta
- ☐ Brovana
- ☐ Indacaterol
- ☐ Arformoterol
- ☐ Striverdi/Olodaterol

LAMA

- ☐ Incruse Ellipta (Umeclidinium)
- ☐ Spiriva Respimat 1.25 mcg (Tiotropium bromide)
- ☐ Spiriva Handihaler (Tiotropium bromide inhalation powder)
- ☐ Spiriva Respimat 2.5 mcg (Tiotropium bromide)
- ☐ Tudorza/Aclidinium

Triple Therapy (fixed-dose combination)

- ☐ Trelegy Ellipta

LTRA

- ☐ Singulair 4 mg (Montelukast)
- ☐ Singulair 5 mg (Montelukast)
- ☐ Singulair 10 mg (Montelukast)
- ☐ Accolate 10 mg (Zafirlukast)
- ☐ Accolate 20 mg (Zafirlukast)
- ☐ Zyflo 600 mg (Zileuton)

Theophylline Preparations

- ☐ Theo-24 100 mg (Theophylline)
- ☐ Theo-24 200 mg (Theophylline)
- ☐ Theo-24 400 mg (Theophylline)
- ☐ Elixophylline 200 mg (Theophylline)
- ☐ Elixophylline 300 mg (Theophylline)
- ☐ Elixophylline 400 mg (Theophylline)
- ☐ Theochron 100mg (Theophylline)
- ☐ Theochron 200mg (Theophylline)
- ☐ Theochron 300mg (Theophylline)
- ☐ Theochron 400mg (Theophylline)

Chronic Add-on Therapy (Macrolides)

- ☐ Azithromycin (Zithromax)

MAINTENANCE PHARMACOLOGIC THERAPY	
☐ Advair HFA 115/21 (Fluticasone/Salmeterol) ☐ Advair HFA 230/21 (Fluticasone/Salmeterol) ☐ Wixela Inhub 100/50 ☐ Wixela Inhub 250/50 ☐ Wixela Inhub 500/50 ☐ Airduo Respiclick 55/14 (Fluticasone/ Salmeterol) ☐ Airduo Respiclick 133/14 (Fluticasone/ Salmeterol) ☐ Airduo Respiclick 232/14 (Fluticasone/ Salmeterol) ☐ Breo Ellipta 100/25 (Fluticasone/Vilanterol) ☐ Breo Ellipta 200/25 (Fluticasone/Vilanterol) ☐ Dulera HFA 100/5 (Mometasone/Formoterol) ☐ Dulera HFA 200/5 (Mometasone/Formoterol) ☐ Symbicort 80/4.5 (Budesonide/Formoterol) ☐ Symbicort 160/4.5 (Budesonide/Formoterol)	☐ Clarithromycin (Biaxin) ☐ Erythromycin (Erythrocin) **Biologics** ☐ Cinqair (reslizumab) ☐ Dupixent (dupilumab) ☐ Fasenra (benralizumab) ☐ Nucala (mepolizumab) ☐ Xolair (omalizumab) ☐ Other:_____

8. SIGNATURES

ASTRAZENECA SIGNATURE(S)

D2287L00028 PRECISION Study 4 Implementation – Version 2, 16 June 2022

Implementation of the US PRECISION AIRQ, Asthma Checklist, and Educational Resources (PRECISION Program) into Clinical Practice Using Telehealth and In-person Platforms

This Community Program intervention Study Protocol version 2 has been subjected to an internal AstraZeneca review.
I agree to the terms of this Study protocol.

AstraZeneca representative

PPD

05-Dec-2023
Date
(Day Month Year)

PPD

06-Dec-2023
Date
(Day Month Year)

EVA-26645-03_Implementation-Study_Final-Study-Protocol-V2.0_16JUN2022_Clean_Signed

Final Audit Report 2023-12-06

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