Alabama Medicaid Pharmacist

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PDL Update

Effective October 1, 2021, the Alabama Medicaid Agency will update the Preferred Drug List (PDL) to reflect the recent Pharmacy and Therapeutics (P&T) Committee recommendations as well as quarterly updates. The updates are listed below:

PDL Additions
AirDuo RespiClick—Respiratory Corticosteroids
Arnuity Ellipta—Respiratory Corticosteroids
Breo Ellipta—Respiratory Corticosteroids
Dymista—EENT Antiallergic Agents
Omnitrope[CC]—Growth Hormones
PDL Deletions
Azelastine/Fluticasone Nasal Spray (generic Dymista)—EENT Antiallergic Agents
Pazeo—EENT Antiallergic Agents

[CC]Preferred with Clinical Criteria

Inside This Issue

Health Information Designs (HID)

Medicaid Pharmacy Administrative Services

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Please fax all prior authorization and override requests *directly* to Health Information Designs at 800-748-0116. If you have questions, please call 800-748-0130 to speak with a call center representative.

Global Initiative for Asthma (GINA) Guideline Update

GINA Releases New Guidance for Asthma Management and Prevention

Established by the World Health Organization (WHO) and National Heart Lung and Blood Institute (NHLBI) in 1993, GINA (the Global Initiative for Asthma) plays an essential role in critically appraising the newest developments in medical literature through its annual update and publication of the *Global Strategy for Asthma Management and Prevention*, also known as the *GINA Report*. The GINA report is based on a systematic, cumulative review of new evidence and serves as a key resource for integrating structured yet adaptable guiding principles for managing asthma. The latest 2021 iteration highlights new perspectives, clarifications, and emerging evidence with regards to severity classification, pharmacologic treatment recommendations, and several other aspects of care.

What's New in GINA 2021?

Severe asthma definition clarified: Severe asthma is defined as asthma that remains uncontrolled despite optimized treatment with high dose inhaled corticosteroid (ICS)-long-acting beta-2 agonist (LABA), or that requires high dose ICS-LABA to prevent it from becoming uncontrolled.

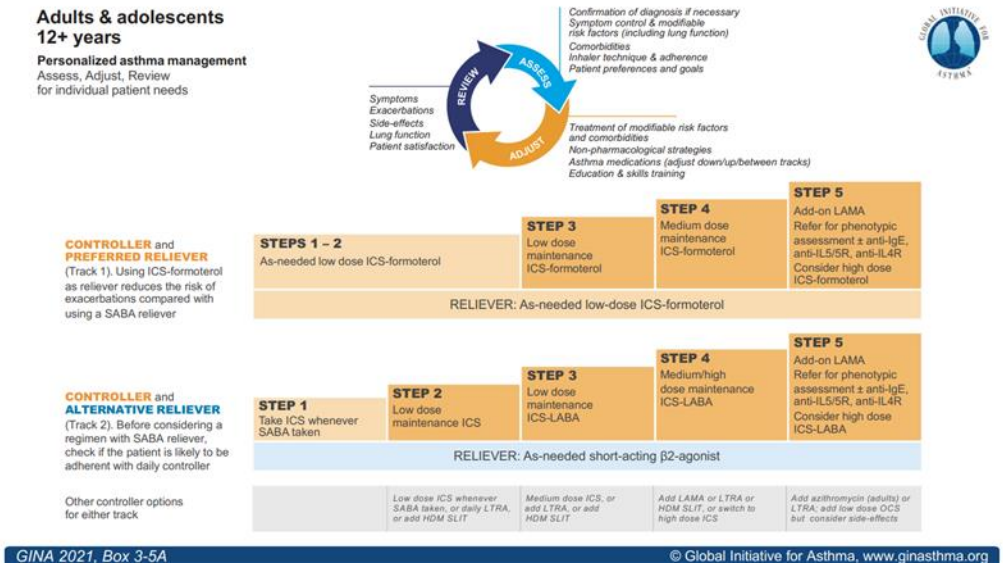
Mild asthma: GINA no longer distinguishes between 'intermittent' and 'mild persistent' asthma. This was an arbitrary distinction and patients with sporadic symptoms can still have severe exacerbations. GINA is currently reviewing the definition of mild asthma and plans to publish the update in a future report.

Treatment tracks for adults and adolescents: Treatment approaches are now presented in the form of two "tracks" with one of the primary distinguishing features being the choice of reliever.

Track 1, the preferred approach, recommends the use of as needed low dose ICS-formoterol as a reliever. The recommendation partially draws support from a large double-blind study where as needed ICS-formoterol produced a 64% lower risk of severe exacerbations when compared to as needed SABA (short-acting beta-2 agonist). Another double-blind study found that as needed ICS-formoterol was non-inferior to maintenance ICS therapy in terms of reducing the risk of severe exacerbations. Additionally, as needed ICS-formoterol demonstrated superiority – with respect to reducing severe exacerbation rates – in 2 open-label randomized controlled trials (RCTs) when compared to maintenance low dose ICS with as needed SABA.

Track 2, the alternative approach, integrates the use of an as needed SABA as a reliever. Although considered secondary to the preferred track, Track 2 could be an option in certain socioeconomic or clinical contexts or situations where Track 1 is not feasible. For example, ICS-formoterol access could be limited due to availability or financial barriers. Additionally, prior to selecting a SABA as a reliever, providers should assess whether the patient has had an exacerbation on their current therapy and gauge the patient's capacity to adhere to the controller component of the regimen.

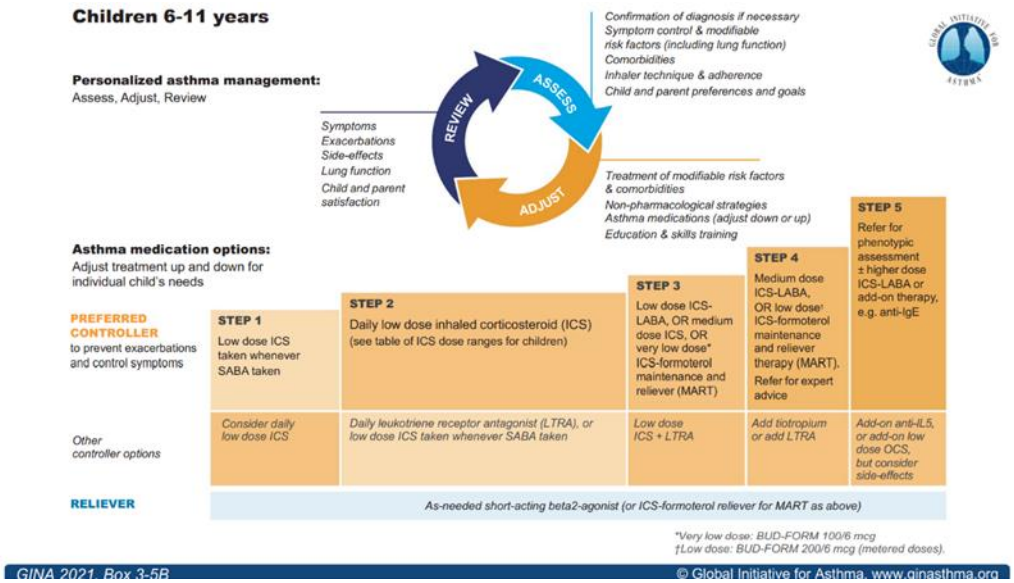
Global Initiative for Asthma (GINA) Guideline Update, continued



Box 3-5A: Personalized management for adults and adolescents to control symptoms and minimize risk

HDM: house dust mite; ICS: inhaled corticosteroid; LABA: long-acting beta-2-agonist; LAMA: long-acting muscarinic antagonist; LTRA: leukotriene receptor antagonist; OCS: oral corticosteroids; SABA: short acting beta-2-agonist; SLIT: sublingual immunotherapy. For recommendations about initial asthma treatment in adults and adolescents, see Box 3-4A (p.53) and 3-4B (p.54).

Treatment steps for children 6-11 years of age: Minor revisions were made to a treatment figure (see Box 3-5B) to align with unchanged recommendations in the corresponding text.



Box 3-5B: Personalized management for children 6-11 years to control symptoms and minimize future risk

BUD-FORM: budesonide-formoterol; ICS: inhaled corticosteroid; LABA: long-acting beta-2-agonist; LTRA: leukotriene receptor antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta-2-agonist. For initial asthma treatment in children aged 6—11 years, see Box 3-4C (p.56) and Box 3-4D (p.57)

Global Initiative for Asthma (GINA) Guideline Update, continued

Long-acting muscarinic antagonists (LAMAs): For patients that are 18 years of age or older, previous recommendations regarding the addition of tiotropium to ICS-LABA have been expanded to include ICS-LABA-LAMA combination inhalers, if asthma is persistently uncontrolled despite treatment with medium or high dose ICS-LABA.

Add-on azithromycin for adults: Azithromycin three days a week has been confirmed as an option for select adults 18 and older with persistent symptomatic asthma despite treatment with a high dose ICS-LABA and only after specialist consultation. Additionally, GINA refined the recommendation language, replacing the broader term "macrolides" with "azithromycin" to more accurately reflect the supporting evidence.

Biologic therapy eligibility and blood eosinophil monitoring: New evidence supports the recommendation for repeat testing of blood eosinophils in patients with severe disease, if low at initial assessment. One study found that 65% of patients with uncontrolled asthma on medium or high dose ICS-LABA experienced shifts in their eosinophil category during 12 months of follow-up.

The full text of the 2021 update and the abridged *GINA 2021 Pocket Guide* can be accessed online at https://ginasthma.org/. Readers are advised to review the complete version for additional details and clinical considerations with respect to recommendations and evidence.

References:

Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available at: http://www.ginasthma.org.

COVID-19 Emergency Expiration Date Extended to October 31, 2021

All previously published expiration dates related to the Coronavirus (COVID-19) emergency are once again extended by the Alabama Medicaid Agency (Medicaid). **The new expiration date is the earlier of October 31, 2021, the conclusion of the COVID-19 National emergency, or any expiration date noticed by the Alabama Medicaid Agency through a subsequent ALERT.**

A listing of previous Provider ALERT and notices related to the health emergency is available by selecting the Agency's COVID-19 page in the link below: https://medicaid.alabama.gov/news_detail.aspx?ID=13729.

During the COVID-19 emergency, it is important to file claims as quickly as possible to ensure payment from Medicaid is made to Medicaid providers close to the date of service. The Centers for Medicare and Medicaid Services has increased the federal matching percentage for the emergency time frame, but states can only receive the increased match on claims that are paid during the emergency. Providers should include appropriate COVID-19 diagnosis code(s) on claims submitted to help with tracking of COVID-19.

Synagis® Criteria

- Due to the COVID-19 public health emergency, the Alabama Medicaid Agency (Medicaid) has determined we will review requests for Synagis® on a case-by-case basis for July, August, and/or September 2021 doses. Use of Synagis® in these months is considered part of the 2020-2021 RSV Season.
- Babies that meet criteria **and have not yet received their 5 doses** for the 2020-2021 season will be considered for July, August, and/or September 2021 doses.
- As per normal criteria, the first dose for newborns must be administered while still inpatient/in the hospital prior to discharge.
- The 2021-2022 season will begin on October 1, 2021. Doses received prior to that date will not be counted towards the baby's doses for the 2021-2022 Synagis® season.
- The approval time frame for Synagis® for the 2021-2022 RSV season will begin October 1, 2021 and will be effective through March 31, 2022. Up to five doses will be allowed per baby in this time frame. There are no circumstances that will result in the approval of a 6th dose.*
- If a dose was administered in an inpatient setting, the date the dose was administered must be included on the PA request form. Subsequent doses will be denied if the baby experiences a breakthrough RSV hospitalization during the RSV season.
- Medicaid updated its prior authorization (PA) criteria for the Synagis® 2021-2022 season. Complete criteria can be found on the website at the following link: https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.10_Synagis.aspx
- **Prescribers,** not the pharmacy, manufacturer, or any other third-party entity, are to submit requests for Synagis® on a specific PA form (form 351) **directly** to Health Information Designs (HID) and completed forms may be accepted beginning September 1, 2021 (for an October 1 effective date). The fax number for Synagis® requests is **1-800-748-0116.**
- All signatures must meet the requirements of Alabama Medicaid Administrative Code Rule 560-X-1-.18(2)(c). Please note that stamped or copied prescriber signatures will not be accepted and will be returned to the provider.
- A copy of the hospital discharge summary from birth or documentation of the first office visit with pertinent information (gestational age, diagnosis, etc.) is required on all Synagis® PA requests.
- If approved, each subsequent monthly dose will require submission of the baby's current weight and last injection date and may be faxed to HID by the prescriber or dispensing pharmacy utilizing the original PA approval letter.
- Prescribers must prescribe Synagis® through a specialty pharmacy. CPT code 90378 remains discontinued for the 2021-2022 season.
- Medicaid is the payor of last resort. Claims must be billed to the primary payor if other third-party coverage exists. Use of NCPDP Other Coverage Codes will be reviewed and inappropriately billed claims will be recouped.

*Medicaid will closely monitor the CDC surveillance information and coordinate with our state pediatric infectious disease/ pulmonary specialist leaders in early 2022 to determine if changes or an extension of the 2021-2022 season is warranted.

Criteria

Alabama Medicaid follows the 2014 American Academy of Pediatrics (AAP) Redbook guidelines regarding Synagis® utilization. For more details, please review a copy of the guidelines found at https://pediatrics.aappublications.org/content/134/2/415. Additional questions regarding criteria can be to directed to HID at 1-800-748-0130.

October 1st Pharmacy Changes

To: Pharmacies, Physicians, Physicians Assistants, Nurse Practitioners, Oral Surgeons, Optometrists, Dentists, FQHCs, RHCs, Mental Health Service Providers and Nursing Homes

Effective October 1, 2021, the Alabama Medicaid Agency will:

1. **Require Prior Authorization (PA) for azelastine/fluticasone nasal spray (generic Dymista). Brand Dymista will be added as preferred.**
2. **Require Dymista to be billed with a Dispense as Written (DAW) Code of 9:** DAW Code of 9 indicates the following: Substitution Allowed by Prescriber but Plan Requests Brand. This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted, but the Plan requests the brand product to be dispensed.
3. **Update the PDL to reflect the quarterly updates. The updates are listed below:**

PDL Additions
AirDuo RespiClick—Respiratory Corticosteroids
Arnuity Ellipta—Respiratory Corticosteroids
Breo Ellipta—Respiratory Corticosteroids
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For additional PDL and coverage information, visit our drug look-up site at https://www.medicaid.alabamaservices.org/ALPortal/NDC%20Look%20Up/tabId/39/Default.aspx.

The Prior Authorization (PA) request form and criteria booklet should be utilized by the prescriber or the dispensing pharmacy when requesting a PA. The PA request form can be completed and submitted electronically on the Agency's website at https://medicaid.alabama.gov/content/9.0_Resources/9.4_Forms_Library/9.4.13_Pharmacy_Forms.aspx. Providers requesting PAs by mail or fax should send requests to:

Health Information Designs (HID)
Medicaid Pharmacy Administrative Services
P.O.Box 3210
Auburn, AL 36832-3210
Fax: 1-800-748-0116
Phone: 1-800-748-0130

Policy questions concerning provider notice should be directed to the Pharmacy Program at (334) 242-5050. Questions regarding PA procedures should be directed to the HID help desk at 1-800-748-0130.

Incomplete PA requests or those failing to meet Medicaid criteria will be denied. If the prescribers believes medical justification should be considered, the prescriber must document this on the form or submit a written letter of medical justification along with the PA form to HID. Additional information may be requested. Staff physicians will review this information.