Maryland
DEPARTMENT OF HEALTH

PHARMACY
News & Views

FALL 2024

Wegovy

The Maryland Medicaid fee-for service (FFS) program as well as the state's nine managed care organizations (MCO) cover Wegovy (semaglutide injection) when prescribed to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight. In accordance with COMAR 10.09.03.05 (A)(14), prescriptions for weight control indications will not be covered at this time. For reference, see Clinical Criteria.

CME/CE SEMINAR

The MDH Office of Pharmacy Services provides live continuing education (CE) programs at no cost in April and October.

Find details at:
https://mmppi.com/live_meetings.htm

Sign up for notifications via Email:
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Response to Retrospective Drug Use Review (RDUR) Intervention Letters and Process

The Maryland Department of Health Medicaid Pharmacy Program Drug Use Review Board (DUR Board) meets quarterly to provide recommendations to the Department on the appropriate use of medications to ensure medical necessity and mitigate the risk of adverse medical outcomes. The DUR Board reviews prescribing and dispensing trends over time to identify and reduce fraud, abuse, gross overuse or inappropriate or unnecessary care. Active, ongoing educational outreach is provided to educate practitioners on common drug therapy problems with the goal of improving prescribing and dispensing practices.

Each month, pharmacists review patient profiles that meet criteria established by the DUR Board. When warranted, physicians and pharmacies are sent educational intervention letters along with a response form to indicate any action taken upon evaluation of the information contained in the letter. It is critically important that completed response forms are returned so that the Program can analyze if any action is taken by the pharmacy and prescriber with regard to the intervention letters.

Patients whose drug utilization continues to be inappropriate despite repeated intervention letters may be restricted to a single pharmacy in an effort to reduce possible misuse or diversion. A recipient who is "restricted" or "locked-in" must obtain all their prescription medications from that single pharmacy until the restriction is lifted. Providers who suspect recipients may have issues with inappropriate medication utilization may also refer such patients directly to the program.

For more information regarding the Corrective Managed Care (CMC) program or to make a referral, please contact the CMC Pharmacist at 410-767-5945.

Respiratory Syncytial Virus (RSV) Updates

Respiratory Syncytial Virus (RSV) is one of several seasonal respiratory viruses that causes serious illness and hospitalizations of infants, older adults, and those who are immunocompromised. Most people infected with RSV will exhibit cold-like upper respiratory symptoms, but RSV can cause more serious lower respiratory tract infections or disease (LRTI or LRTD) such as bronchiolitis or pneumonia especially in infants under 6 months and patients older than 65 years of age with certain risk factors. The CDC reports that, "two to three percent of infants under 6 months of age are hospitalized with RSV every year."[1] RSV follows a seasonal pattern typically beginning in October, peaking in December, and ending in April. Three vaccines are FDA approved to protect against severe RSV; Abrysvo, Arexvy, and mRESVIA.[2-4] See the table below for a comparison of the vaccines.

The listed approved vaccines are not indicated for use in infants and young children at risk of severe LRTD due to RSV. To prevent severe RSV in this population, either maternal RSV vaccination or infant immunization with the RSV monoclonal antibody is recommended. Although nearly every child will get RSV by the time they are two years old, the immunity developed following the infection does not last.[1] Studies have shown that antibodies normalize within six months of RSV infection, and reinfection can occur within two months of last infection.[5,6] Given that innate, or nonspecific immunity may not provide protection against RSV and the lack of a vaccine approved for this patient population, monoclonal antibodies (MAbs) provide protection through passive immunity.[6]

	Abrysvo[2]	**Arexvy[3]**	**mRESVIA[4]**
Mechanism	recombinant RSV F protein antigen	recombinant RSV F protein antigen Adjuvanted	nucleoside modified mRNA encoding the RSV F glycoprotein
RSV subtype(s)	RSV-A and RSV-B	RSV-A	RSV-A
Formulation	Act-O-Vial reconstitution	Powder for reconstitution	Pre-filled syringe
Storage	Refrigerate between 36°F and 46°F. May store reconstituted vaccine at room temperature 59°F to 86°F for up to 4 hours before use.	Refrigerate between 36°F and 46°F. May store reconstituted vaccine at room temperature 59°F to 86°F for up to 4 hours before use.	Frozen between -40°F and 5°F, may be refrigerated between 36°F and 46°F for up to 30 days.
Approved Uses:			
Pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age	✓		
Adults 50 through 59 years of age and at increased risk for LRTD caused by RSV		✓	
Adults 60 years of age and older	✓	✓	✓

Respiratory Syncytial Virus (RSV) Updates *(continued)*

The original MAb for RSV, palivizumab (Synagis), is an RSV F protein inhibitor that was approved in 1998. Palivizumab is indicated for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients:

1. With a history of premature birth (less than or equal to 35 weeks gestational age) and who are six months of age or younger at the beginning of RSV season
2. With bronchopulmonary dysplasia (BPD) that required medical treatment within the previous six months and who are 24 months of age or younger at the beginning of RSV season
3. With hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

Palivizumab is given as a 15 mg per kg of body weight intramuscular injection administered before the beginning of the RSV season and then given monthly throughout the RSV season for up to five doses.[7] Palivizumab decreases RSV hospitalizations in high-risk infants up to 55%, but it is expensive, requires repeated administrations, and is approved for use in a limited number of the total at risk patients.[8]

In 2023 a new MAb, nirsevimab (Beyfortus), was approved for use. Nirsevimab is also an RSV F protein-directed fusion inhibitor and is indicated for the prevention of RSV lower respiratory tract disease in:

1. Neonates and infants born during or entering their first RSV season.
2. Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

Nirsevimab is given as a one-time seasonal intramuscular injection with the dose (50 mg, 100 mg, or 200 mg) based on body weight and age.[9] There are several reasons to use nirsevimab over palivizumab. The longer half-life eliminates the need for multiple injections, it is indicated for use in a much larger portion of the at-risk population, is a fraction of the cost, and has been shown to decrease RSV hospitalizations by 75% or more.[1,8-10] Adverse reactions are similar between the two agents with rash, fever, and injection site reactions most commonly reported.[7,9] Based on the recent developments of vaccines and MAbs we can hope to see a significant decrease in the number of older adults and infants affected by RSV-related LRTD.

References

1. U.S. Centers for Disease Control and Prevention. Respiratory Syncytial Virus (RSV). https://www.cdc.gov/rsv/index.html (accessed 2024 Sept 6).
2. Abrysvo [package insert]. New York, NY: Pfizer Inc.; August 2024.
3. Arexvy [package insert]. Rixensart, Belgium: GlaxoSmithKline Biologicals; August 2024.
4. mRESVIA [package insert]. Princeton, NJ: ModernaTx, Inc; May 2024.
5. Hall CB, Walsh EE, Long CE, Schnabel KC. Immunity to and frequency of reinfection with respiratory syncytial virus. J Infect Dis. 1991 Apr; 163(4):693-8.
6. Habibi MS, Jozwik A, Makris S et al. Impaired antibody-mediated protection and defective IgA B-cell memory in experimental infection of adults with respiratory syncytial virus. Am J Respir Crit Care Med. 2015 May 1; 191(9):1040-9.
7. Synagis [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; November 2021.
8. Sun M, Lai H, Na F et al. Monoclonal antibody for the prevention of respiratory syncytial virus in infants and children. JAMA Netw Open. 2023; 6(2):e230023.
9. Beyfortus [package insert]. Södertälje, Sweden: AstraZeneca AB; July 2023.
10. Hammitt LL, Dagan R, Yuan Y et al. Nirsevimab for prevention of RSV in healthy late-preterm and term infants. N Engl J Med. 2022 Mar 3; 386(9): 837-46.

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- **Conduent Technical Assistance**
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  833-325-0105
  Monday-Friday, 8:00 am - 5:00 pm
- **Kidney Disease Program**
  410-767-5000 or 5002
  Monday-Friday, 8:00 am - 5:00 pm
- **Breast and Cervical Cancer Diagnosis and Treatment**
  410-767-6787
  Monday-Friday, 8:00 am - 4:30 pm
- **Maryland AIDS Drug Assistance Program**
  410-767-6535
  Monday-Friday, 8:30 am - 4:30 pm
- **Peer Review Program**
  855-283-0876
  Monday-Friday, 8:00 am - 6:00 pm

POS Coordination of Benefits (COB) Procedures

Maryland Medicaid participants may have additional primary insurance coverage for prescriptions and other services. If the recipient has other insurance or coverage, or if any other person is obligated either legally or contractually to pay for or to reimburse for covered pharmacy services, COMAR 10.09.03.07 requires the provider to bill all appropriate insurance carriers before requesting payment from Maryland Medicaid. COMAR 10.09.03.03 requires providers to maintain adequate records and make them available to the Department upon request. Maryland Medicaid is the payer of last resort, and providers must follow appropriate use of NCPDP coverage codes. The Department may request the provider supply records to verify any charge to Maryland Medicaid. For assistance with COB claims processing, please contact Conduent Technical Assistance at (800) 932-3918. A listing of NCPDP "Other Coverage" Codes and their appropriate use is below.

Code	Proper Use
1 - No Other Coverage Identified	Provider has confirmed patient does not have valid other insurance.
2 - Other Coverage Exists - Payment Collected	Claim has adjuidcated through primary payer, who has paid toward the claim.
3 - Other Coverage Exists - This Claim Not Covered	Only to be used when primary payer requires prior authorization, which has been denied.
4 - Other Coverage Exists - Payment Not Collected	Primary payer has paid $0 due to deductible, cost of claim is less than primary payer's copay, etc.