



## OCTOBER 2024

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

**Clinical PA Fax (PDL)** 1-800-424-5739 24 Hours A Day, 7 Days a Week

## Division of Medical

Services Pharmacy Unit P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

Table of Contents DRUG UTILIZATION REVIEW (DUR) BOARD UPDATE	. 1
DAW CODE UPDATE:	
PREGNANCY COPAY OVERRIDE:	. 2
RECOMMENDATIONS FOR THE PREVENTION OF RSV DISEASE	. 2
NONALCOHOLIC STEATOHEPATITIS (NASH)	. 5
NEW FDA APPROVED MEDS 2024	. 9
USEFUL LINKS/PHONE NUMBERS	10

#### DRUG UTILIZATION REVIEW (DUR) BOARD UPDATE

DIGG OTHER (DOIL)				
The following will be presented during the October 16, 2024 DUR Board meeting.				
Preferred Drug List Review	Overactive bladder, antipsychotics, CGRP antagonists			
Proposed Point-of-Sale Changes	Therapeutic duplication on opioid use disorder meds			
Manual Review PA Criteria	Voquezna®, OFEV®, Esbriet®, Evrysdi®, Salicate <sup>™</sup> , Alkindi, Xolremdi <sup>™</sup> , Iqirvo®, Livdelzi®, Ohtuvayre <sup>™</sup> , Winrevair <sup>™</sup> , and Dupixent® for COPD			

https://ar.primetherapeutics.com/documents/d/arkansas/dur-board-agenda-for-oct-16-2024

### DAW CODE UPDATE:

In an effort to ensure pharmacies are being reimbursed for pharmacy claims properly, only DAW codes 0,1, & 9 will be allowed effective 10/1/2024.

- DAW Code 0 No Product Selection Indicated
  - Allowed for all drugs except for Brand Medically Necessary Medications (DAW Code 1 required) and State Supported Brands (DAW Code 9 required).
  - Please verify when using DAW 0 that the NDC being billed is either a Generic or a Single Source Brand. If DAW code 0 is used and the NDC is not a generic or single source brand, payment will be based on generic pricing.
  - DAW Code 1 Substitution not allowed by prescriber
    - Allowed with approved prior authorization
    - Initial reject message prior to PA approval will read "PA Required" and "Prescriber PA Required for Brand Name"
- DAW Code 2 Substitution allowed-patient requested product dispensed
  - Code will no longer be allowed
  - Reject message will read "DAW Code Value Not Supported"
- DAW Code 3 Substitution allowed-pharmacist selected product dispensed
  - Code will no longer be allowed
  - Reject message will read "DAW Code Value Not Supported"
- **DAW Code 4** Substitution allowed-generic drug not in stock
  - $\circ$   $\,$  Code will no longer be allowed
  - Reject message will read "DAW Code Value Not Supported" and "Contact Help Desk for Assistance".
- DAW Code 5 Substitution allowed-brand drug dispensed as a generic
  - Code will no longer be allowed
  - Reject message will read "DAW Code Value Not Supported"





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

### **Clinical PA Fax (PDL)**

1-800-424-5739 24 Hours A Day, 7 Days a Week

#### Division of Medical Services Pharmacy Unit

P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

#### DAW Code 6 – Override

- Code will no longer be allowed
- Reject message will read "DAW Code Value Not Supported"
- DAW Code 7 Substitution NOT allowed-brand drug mandated by law
  - Code will no longer be allowed
  - Reject message will read "DAW Code Value Not Supported"
  - DAW Code 8 Substitution allowed-generic drug not available in marketplace
  - o Code will no longer be allowed
  - Reject message will read "PA required"
- If generic has a shortage issue, contact the Help Desk at 800-424-7895 for assistance
- DAW Code 9 Substitution allowed by prescriber but plan requests brand
  - Allowed for use when Arkansas Medicaid requires brand name products as preferred when generics are on the market
  - Using DAW 9 for plan prefers brand (PPB) products ensures that pharmacies are reimbursed at the brand rate
  - If not a PPB product, reject message will read "Prior Authorization Required" and "State Supported Preferred Brand Only"
  - Please refer to the State Supported Brand Medications document for a complete list of the Arkansas Supported Brands.

For any questions, contact the Prime Therapeutics State Government Solutions Help Desk at 800-424-7895.

#### PREGNANCY COPAY OVERRIDE:

Pharmacies have the ability to bypass a pregnant patient's copay using Z33.1. This is done by applying the pregnancy ICD-10 Z33.1 on the member profile at POS. Once the Pharmacist places the code on the claim, the copay is bypassed (\$0).

#### **RECOMMENDATIONS FOR THE PREVENTION OF RSV DISEASE:**

https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV?autologincheck=redirected

The American Academy of Pediatrics (AAP) recommends nirsevimab, consistent with the Advisory Committee on Immunization Practices (ACIP),<sup>1,2</sup> for:

 Infants aged <8 months born during or entering their first RSV season whose pregnant parent did not receive RSVpreF vaccine, whose pregnant parent's RSVpreF vaccination status is unknown, or who were born <14 days after the pregnant parent's RSVpreF vaccination.

Nirsevimab is not needed for most infants aged <8 months whose pregnant parent received RSVpreF vaccine  $\geq$ 14 days before giving birth. Nirsevimab may be considered for infants born to a vaccinated pregnant parent in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted. These situations include, but are not limited to:

 infants born to pregnant people who might not have mounted an adequate immune response to vaccination (e.g., persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (e.g., persons living with HIV infection);





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

Clinical PA Fax (PDL) 1-800-424-5739 24 Hours A Day, 7 Days a Week

#### Division of Medical Services Pharmacy Unit

P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

- infants who might have experienced loss of transplacentally acquired antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation;
- and infants with substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease or intensive care admission requiring oxygen at hospital discharge).
- Infants and children 8 through 19 months of age who are at increased risk of severe RSV disease and entering their second RSV season, including those recommended by the AAP to receive palivizumab,3 regardless of RSV vaccination status of the pregnant parent. This includes the following:
  - Infants and children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season.
  - o Infants and children who are severely immunocompromised.
  - Infants and children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is less than the 10th percentile.
  - American Indian and Alaska Native children.

#### Equity and Access Considerations

Equity in access to nirsevimab is of the highest priority to the AAP. If nirsevimab is not available or not feasible to administer, high-risk infants who are recommended to receive palivizumab in the first or second year of life should receive palivizumab, as previously recommended,3 until nirsevimab becomes available. High-risk infants whose pregnant parent received a recommended RSV vaccine  $\geq$ 14 days prior to delivery do not require palivizumab, except in the rare circumstances as described above. The following are considerations with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season:

- If nirsevimab is administered, palivizumab should not be administered later that season.
- If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered. There is no minimum interval between the last dose of palivizumab and the dose of nirsevimab. Because protection from palivizumab wanes after 30 days, nirsevimab should be administered no later than 30 days after the last palivizumab dose, when possible.
- If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

If nirsevimab supply is limited and the patient is not eligible for palivizumab, nirsevimab should be prioritized to protect infants and children at the highest risk for severe RSV disease using the following principles: first by high-risk conditions, and then by age, prioritizing the youngest infants first.

#### **Administration Considerations**

Clinicians should aim for administration of nirsevimab in the first week of life for infants who are recommended to receive nirsevimab and are born shortly before and during the RSV season based on geography. Nirsevimab can be administered during the birth hospitalization or in the outpatient setting. Infants with prolonged birth hospitalizations





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

#### Clinical PA Fax (PDL) 1-800-424-5739 24 Hours A Day, 7 Days a Weak

7 Days a Week

#### Division of Medical Services Pharmacy Unit

P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

# because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge from the hospital.

- Nirsevimab should be administered to other eligible infants and toddlers shortly before or during the RSV season, as soon as nirsevimab is available.
- While the timing of the onset and duration of RSV season may vary, nirsevimab may be administered from October through the end of March in most of the continental United States. The timing of the onset, peak, and decline of RSV activity vary geographically, and providers may adjust timing of administration based on guidance from public health authorities (e.g., CDC, health departments) or regional medical centers. Only children who meet high-risk criteria should receive more than one dose of nirsevimab – one dose in their first RSV season and one dose in their second RSV season.
- NOTE: For Arkansas, the typical RSV season runs from November 1 to March 31.
- In accordance with the CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. In clinical trials, when nirsevimab was administered concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the concomitantly administered regimen was similar to that of the childhood vaccines administered alone. When concomitantly administered, nirsevimab is not expected to interfere with the immune response to other vaccines.

#### ARKANSAS MEDICAID RSV PREVENTION COVERAGE FOR CHILDREN:

- Nirsevimab is a monoclonal antibody product that is a passive immunization. While not technically a "vaccine" in a traditional sense (active immunization), it is being used in a manner similar to routine childhood vaccines and may be referred to as a vaccine by some entities. Nirsevimab confers long-lasting protection from RSV, with protection expected to last at least 5 months (about the length of a typical RSV season). Nirsevimab is part of the Vaccines for Children program, and a claim will be processed as a medical bill; not a pharmacy claim. CPT codes for medical billing:
  - 90380: Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use
  - 90381: Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use
  - Palivizumab is a humanized monoclonal antibody produced by recombinant DNA technology that is indicated for the prevention of serious lower respiratory tract diseases caused by respiratory syncytial virus (RSV). Per the above guidance, palivizumab may have limited usage during this RSV season. If deemed medically necessary over nirsevimab, a prior authorization request must be submitted to Arkansas Medicaid with the attached form. https://ar.primetherapeutics.com/documents/268611/269351/ARRx\_Synagis\_PA\_Form/d952ef7d-0bf5-12b3-59ab-93fafcca34f7

#### ARKANSAS MEDICAID RSV PREVENTION COVERAGE FOR ADULTS:

- ABRYSVO is a vaccine indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Also, ABRYSVO is indicated for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.
  - For members who are also VFC eligible the provider will bill 90678 with VFC modifiers.
  - For adults, the provider will bill 90678 and use 90471/90472 for administration
- AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:
  - individuals 60 years of age and older; the provider will bill 90679 and 90471/90472 for administration





### OCTOBER 2024

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

**Clinical PA Fax (PDL)** 1-800-424-5739 24 Hours A Day, 7 Days a Week

#### Division of Medical Services Pharmacy Unit

P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays MRESVIA is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

- for ages 60+ requires manual pricing, majority of providers will submit clinical and invoice when they initially bill. If it denies for (error code 6000- manual pricing ), they will then submit documentation required per explanation of benefits
- Providers will bill 90471 for administration.

#### References

- Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72(34):920-925
- Fleming-Dutra KÉ, Jones JM, Roper LE, et al. Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices—United States, 2023. MMWR Morb Mortal Wkly Rep. ePub: 6 October 2023
- 3. American Academy of Pediatrics. Respiratory syncytial virus. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book: 2021 Report of the Committee on Infectious Diseases. 32nd ed. American Academy of Pediatrics; 2021:628-636
- 4. <u>https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e5c837e7-41e8-496a-9c85-6b0453b35948</u>
- 5. <u>https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e50f275-002e-413f-a840-66ee3cb3740c</u>
- 6. <u>https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=be18292e-b1a2-4815-a0ed-003efaa6bea3</u>
- 7. <u>https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2f08fa60-f674-432d-801b-1f9514bd9b39</u>
- 8. <u>https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3a0096c7-8139-44cd-bba4-520ab05c2cb2</u>

#### NONALCOHOLIC STEATOHEPATITIS (NASH):

Written by Susana Granell-Bellmunt, RPh, PhD **DEFINITION** 

Please note that NAFLD and NASH have been renamed. NAFLD (nonalcohol associated fatty liver disease) is now called MASLD (metabolic dysfunction associated steatotic liver disease). NASH (Nonalcoholic steatohepatitis) has been renamed MASH (metabolic dysfunction associated steatohepatitis). In MASLD, hepatic steatosis (fat accumulation in liver cells) is present without evidence of inflammation. MASLD can progress to MASH which is the more severe condition. In MASH, hepatic steatosis is associated with lobular inflammation and apoptosis that can lead to fibrosis and cirrhosis. MASLD occurs in patients with little or no history of alcohol consumption.

#### **EPIDEMIOLOGY**

The prevalence of MASLD and MASH is rising worldwide alongside increases in the prevalence of obesity and metabolic comorbid disease. The prevalence of MASLD in adults is estimated to be 25%–30% in the general population. MASH is present in 1.5% to 6.5% of U.S. adults. MASH prevalence is projected to increase by 63% by 2030. MASH is expected to become the leading cause of liver transplantation in the United States. The associated economic burden attributable to MASH is substantial.





## **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

Clinical PA Fax (PDL) 1-800-424-5739 24 Hours A Day, 7 Days a Week

# Division of Medical

Services Pharmacy Unit P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

#### PATHOGENESIS

The pathogenesis of MASLD is complex and is not fully understood. Insulin resistance has been proposed to have a key role in the development of hepatic steatosis and, potentially, steatohepatitis. Obesity and T2DM, conditions associated with peripheral insulin resistance, are frequently observed in patients with MASLD. However, not all patients with MASH exhibit insulin resistance. This suggests that MASH may be a heterogeneous syndrome with more than one cause. It has also been proposed that additional oxidative injury may be required to progress to steatohepatitis. Hepatic iron, gut hormones, antioxidant deficiencies, and intestinal bacteria have all been implicated in the pathogenesis of MASLD. Differences in genetic, dietary, behavioral, and environmental factors influence disease course.

The most important comorbid conditions associated with MASLD include obesity, type 2 diabetes Mellitus (T2DM), hypertension, dyslipidemia, obstructive sleep apnea, cardiovascular disease, and chronic kidney disease. In addition, MASLD has been reported in patients with hypothyroidism, hypogonadism, growth hormone (GH) deficiency, and polycystic ovarian syndrome (PCOS). Several Drugs with potential mechanistic links to hepatic steatosis or steatohepatitis include amiodarone, 5 -FU, irinotecan, tamoxifen, methotrexate, and corticosteroids.

#### DIAGNOSIS

Prompt diagnosis and management are critical to preventing MASLD from progressing to more severe forms of liver disease. Most patients with MASLD are asymptomatic and can go largely undiagnosed. Some patients with MASH may report fatigue, malaise, and vague right upper abdominal discomfort. Asymptomatic patients are usually identified when laboratory testing shows elevated liver enzymes or when abdominal imaging shows liver steatosis as an incidental finding. Differential diagnosis using other clinical labs, imaging and biopsy may be necessary to exclude other causes of liver disease and to establish the diagnosis of MASLD. Patients who develop cirrhosis may have hematologic abnormalities such as low platelets and neutropenia. Patients may present with decompensated cirrhosis, but it is uncommon.

Targeted screening of high-risk populations, such as those with T2DM, obesity with metabolic complications, a family history of cirrhosis, or significant alcohol consumption (due to its capacity to accelerate disease progression), may identify those with asymptomatic but clinically significant fibrosis. Early identification of such at-risk patients allows for interventions that may prevent future hepatic complications.

A multi-step approach is recommended in patients with MASLD. First, an established nonpatented blood-based score, such as FIB-4, should be used. Thereafter, established imaging techniques, such as liver elastography, are recommended as a second step to further clarify the fibrosis stage if fibrosis is still suspected or in high-risk groups. Useful tools and algorithms to diagnose and manage MASLD in primary care and endocrinology practice settings can be found in American and European guidelines. <u>Hepatology (lww.com)</u> and <u>EASL-EASD-EASO</u> <u>Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD) (journal-of-hepatology.eu)</u>

# MANAGEMENT

### Non-Pharmacological treatment:

Lifestyle modifications: This is the first line of treatment MASLD and MASH and include:
 \*Weight loss achieved with a balance of calorie reduction, macronutrient composition and
 exercise. Patients with MASLD who are overweight or obese should be prescribed a diet that
 leads to a caloric deficit. When possible, diets with limited carbohydrates and saturated fat
 and enriched with high fiber and unsaturated fats (e.g., Mediterranean diet) should be
 encouraged due to their additional cardiovascular benefits. Patients with MASLD should be





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

Clinical PA Fax 1-800-424-7976 24 Hours A Day, 7 Days a Week

#### Clinical PA Fax (PDL)

1-800-424-5739 24 Hours A Day, 7 Days a Week

### Division of Medical

Services Pharmacy Unit P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays strongly encouraged to increase their activity level to the extent possible. Individualized prescriptive exercise and nutrition recommendations may increase sustainability and have benefits independent of weight loss.

- \*Abstinence from alcohol. Alcohol can be a cofactor for liver disease progression, and intake should be assessed on a regular basis. Patients with clinically significant hepatic fibrosis (≥ F2) should abstain from alcohol use completely.
- \* Updated Immunizations (and specifically relevant, against Hepatitis A and B virus).

#### 2. Additional non-pharmacologic treatments may include:

\*Bariatric surgery should be considered as a therapeutic option in patients who meet criteria for metabolic weight loss surgery, as it effectively resolves MASLD or MASH in most patients without cirrhosis and reduces mortality from CVD and malignancy.

#### Pharmacological treatment:

• REZDIFFRA® (resmetirom) is indicated in conjunction with diet and exercise for the treatment of adults with MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

This indication is approved under accelerated approval based on improvement of NASH and fibrosis Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

\*Patients with cirrhosis were excluded from published clinical trials, but ongoing trials are evaluating safety and efficacy of resmetirom in such patients.

Resmetirom is a partial agonist of the thyroid hormone receptor-beta (THR- $\beta$ ). THR- $\beta$  is the major form of THR in the liver, and stimulation of THR- $\beta$  in the liver reduces intrahepatic triglycerides.

Prior to prescribing resmetirom, clinicians should review the patient's prescribed medications, over-the-counter medications, and dietary supplements. Resmetirom should not be used with OATP 1B1, IB3 inhibitors (e.g., cyclosporine) or strong CYP2C8 inhibitors (e.g., gemfibrozil). Data from clinical trials suggested that resmetirom improved MASH and stage of liver fibrosis. In a trial comparing resmetirom (80 or 100 mg) with placebo in 966 adults with biopsy-confirmed MASH and a liver fibrosis stage of F1B, F2, or F3, resmetirom resulted in higher rates of MASH resolution at 52 weeks. In addition, resmetirom resulted in higher rates of improving fibrosis by at least one stage. Diarrhea and nausea were reported more frequently in the treatment groups.

Up until recently, there were no FDA-approved medications for the treatment of MASLD, however, drugs approved to treat associated comorbidities with potential benefit in MASLD may be considered in the appropriate clinical setting:

- GLP-1 receptor agonists for patients with T2DM/obesity biopsy-proven MASH with fibrosis stage ≥F2 who do not achieve weight loss with lifestyle interventions.
- Vitamin E (off-label, support in the compendia) may be considered in select individuals as it improves MASH in some patients without diabetes. Some studies suggest that vitamin E improves steatosis and inflammation in such patients. However, because data are mixed and there are potential safety concerns with high-dose vitamin E. Potential risks and benefits of vitamin E therapy should be discussed. Vitamin E should be avoided in male patients with either a personal history or strong family history of prostate cancer.
   Pioglitazone (off-label, support in the compendia) improves MASH and may be considered





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

**Clinical PA Fax (PDL)** 1-800-424-5739 24 Hours A Day,

7 Days a Week

Division of Medical Services Pharmacy Unit

P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays for patients with MASH in the context of patients with T2DM.

#### Other considerations

Available data on GLP-1 receptor agonists, pioglitazone, and vitamin E do not demonstrate an antifibrotic benefit, and these compounds have not been carefully studied in patients with cirrhosis.

Metformin, UDCA, DPP-4, statins, and silymarin are well studied in MASH and should not be used as a treatment for MASH as they do not offer a meaningful histological benefit. Statins are safe and recommended for CVD risk reduction in patients with MASLD across the disease spectrum, including compensated cirrhosis. Limited data exist on the safety and efficacy of statins in patients with decompensated cirrhosis, although statin use could be considered in patients with high CVD risk with careful monitoring. Hypertriglyceridemia can be managed through lifestyle changes and supplementation with omega-3 fatty acids, icosapent ethyl, or fibrates.

Finally, although MASLD is commonly associated with obesity, it can also occur in patients with normal BMI. Genetic factors likely play a significant role in this population, but the overall genetic contribution to MASLD requires further study. Management of MASLD in patients without obesity can be clinically challenging. Recommending weight loss may not be appropriate for lean patients with MASLD, but dietary modifications and exercise in this group may be beneficial.

- 1) <u>A multisociety Delphi consensus statement on new fatty liver disease nomenclature -</u> <u>PubMed (nih.gov)</u>
- 2) <u>Management of metabolic dysfunction-associated steatotic liver disease (nonalcoholic fatty liver disease) in adults UpToDate</u>
- 3) AASLD Practice Guidance on the clinical assessment and manag... : Hepatology (lww.com)
- 4) <u>Pathogenesis of metabolic dysfunction-associated steatotic liver disease (nonalcoholic fatty liver disease) UpToDate</u>
- 5) <u>Metabolic Dysfunction-Associated Steatotic Liver Disease and Metabolic Dysfunction-Associated Steatohepatitis: The Patient and Physician Perspective PMC (nih.gov)</u>
- 6) <u>DailyMed REZDIFFRA- resmetirom tablet, coated REZDIFFRA- resmetirom tablet, coated REZDIFFRA- resmetirom tablet, coated (nih.gov)</u>
- 7) <u>EASL-EASD-EASO Clinical Practice Guidelines on the management of metabolic</u> <u>dysfunction-associated steatotic liver disease (MASLD) (journal-of-hepatology.eu)</u>





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

Clinical PA Fax (PDL) 1-800-424-5739 24 Hours A Day, 7 Days a Week

#### Division of Medical Services Pharmacy Unit

P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

NEW FDA		
APPROVED	INDICATION	AR MEDICAID COVERAGE
MEDS 2024		
Rivfloza™	Treat primary hyperoxaluria type 1	Manual review with criteria determined by the DUR Board
Agamree®	Treatment of Duchenne Muscular Dystrophy	Manual review with criteria determined by the DUR Board
Filsuvez®	Treat dystrophic and junctional epidermolysis bullosa	Manual review with criteria determined by the DUR Board
Duvyzat™	Treat Duchenne Muscular Dystrophy	Manual review with criteria determined by the DUR Board
Winrevair™	Treat pulmonary arterial hypertension	Nonpreferred in the PAH class
Rezdiffra™	Treat noncirrhotic nonalcoholic steatohepatitis	Manual review with criteria determined by the DUR Board
Vafseo®	Anemia due to CKD	Manual review with criteria determined by the DUR Board
Opsynvi™	Treat pulmonary arterial hypertension	Nonpreferred in the PAH class
Tyenne®	Biosimilar to Actemra®	Nonpreferred in the targeted immunomodulators class
Eohilia™	Treat eosinophilic esophagitis	Point-of-sale edit looking for proper diagnosis
Simlandi®	Biosimilar to Humira®	Nonpreferred in the targeted immunomodulators class
Jubbonti®	Biosimilar to Prolia®	Nonpreferred in the osteoporosis class with Prolia® criteria
Wyost®	Biosimilar to Xgeva®	Manual review with Xgeva® criteria
Tryvio™	Treat hypertension	Nonpreferred in the HTN class with criteria
Voydeya™	Treat paroxysmal nocturnal hemoglobinuria	Manual review with criteria determined by the DUR Board
Anktiva®	Bladder Cancer	Excluded in pharmacy; medical review only
Ojemda™	Pediatric low-grade glioma	Manual review based on the oncology policy
Xolremdi™	WHIM Syndrome	Manual review with criteria determined by the DUR Board
Imdelltra™	Extensive stage SCLC	Excluded in pharmacy; medical review only
Rytelo™	Myelodysplastic syndrome	Excluded in pharmacy; medical review only
lqirvo®	Primary biliary cholangitis	Manual review with criteria determined by the DUR Board
Sofdra™	Hyperhidrosis	Manual review with criteria determined by the DUR Board
Piasky®	Paroxysmal nocturnal hemoglobinuria	Manual review with criteria determined by the DUR Board
Ohtuvayre™	COPD	Manual review with criteria determined by the DUR Board





## OCTOBER 2024

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

Clinical PA Fax (PDL) 1-800-424-5739 24 Hours A Day, 7 Days a Week

Division of Medical Services Pharmacy Unit P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

Kisunla™	Alzheimer's disease	Excluded in pharmacy; medical review only
Voranigo®	Astrocytoma/oligodendroglio ma	Manual review based on the oncology policy
Yorvipath®	Hypoparathyroidism	Manual review with criteria determined by the DUR Board
Livdelzi®	Primary biliary cholangitis	Manual review with criteria determined by the DUR Board
Lacluze™	NSCLC	Manual review based on the oncology policy
Ebglyss™	Atopic dermatitis	Nonpreferred in the AD class with criteria
Miplyffa™	Niemann-Pick disease	Manual review with criteria determined by the DUR Board
Aqneursa™	Niemann-Pick disease	Manual review with criteria determined by the DUR Board
Cobenfy™	Schizophrenia	TBD

#### USEFUL LINKS/PHONE NUMBERS DHS webpage

(contains official notices and other information for providers and clients) https://humanservices.arkansas.gov/divisions-shared-services/medical-services/helpfulinformation-for-providers/

#### DHS provider manuals

https://humanservices.arkansas.gov/divisions-shared-services/medical-services/helpfulinformation-for-providers/manuals/

#### Arkansas Foundation for Medical Care (AFMC)

If you are having billing issues for vaccines and other medical professional claims, contact AFMC or your outreach specialist. <u>https://www.afmc.org/</u> <u>https://medicaid.afmc.org/services/arkansas-medicaid-management-information-system</u> **AFMC PHONE:** 479-649-8501 **AFMC FAX:** 479-649-0799

#### DME billing assistance

Kara Orvin phone: 501-630-6064 Kara.L.Orvin@dhs.arkansas.gov

#### Third Party Liability (TPL) phone: 501-537-1070

#### Provider Assistance Center (PAC)

For questions about individual or pharmacy enrollment, please contact the provider assistance center. Provider Assistance Center (PAC) in Arkansas: 800-457-4454

Provider Assistance Center (PAC) from out of state: 501-376-2211

#### Opioid guidance

- https://ar.primetherapeutics.com/provider-documents
- https://www.cdc.gov/drugoverdose/
- https://www.samhsa.gov/medication-assisted-treatment





### **OCTOBER 2024**

THE NUMBERS LISTED BELOW ARE FOR FEE-FOR-SERVICE (FFS) SUPPORT

Prime Therapeutics Pharmacy Support Center (Pharmacy, Member, and Prior Authorization) 1-800-424-7895 Monday – Friday 8:00 a.m. – 5:00 p.m., Central Time (CT) excluding State holidays

#### **Clinical PA Fax**

1-800-424-7976 24 Hours A Day, 7 Days a Week

#### Clinical PA Fax (PDL)

1-800-424-5739 24 Hours A Day, 7 Days a Week

#### Division of Medical

Services Pharmacy Unit P.O. Box 1437, Slot S-415 Little Rock, AR 72203 Fax: 501-683-4124 OR 800-424-5851 Phone: 501-683-4120 Monday – Friday 8:00 a.m. – 4:30 p.m., Central Time (CT) excluding State holidays

- The Dangers Of Mixing Benzodiazepines With Opiates Opioid Treatment
- https://www.rehabs.com/blog/the-polypharmacy-overdose-a-killer-trend/
- https://narcansas.com/
- https://afmcanalytics.maps.arcgis.com/apps/MapSeries/index.html?appid=2977d338de974451af 5ce8ff24d2a30c
- https://www.cdc.gov/overdose-prevention/

#### DUR BOARD MEETING DATES

October 16, 2024 January 15, 2025 April 16, 2025 July 16, 2025 October 15, 2025

Our next newsletter will be posted in January 2025. The Arkansas Medicaid Pharmacy Unit wishes you a wonderful holiday season spent with family and friends.