



Division of Medical Services
Pharmacy Program



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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

FROM: Cynthia Neuhofer, Pharm.D. Division of Medical Services Pharmacy Program

DATE: February 26, 2020

SUBJ: AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board January 15, 2020 meeting for the following: Manual review criteria for: Esbriet®, Ofev®, Temodar®, Nouriaz™, Egaten®, Trikafta™, FEIBA, NovoSeven RT, Pretomanid, Nayzilam®, Oxbryta®; Point-of-Sale criteria changes for: Entresto®, Sensipar®, Procrit®, Epogen® and medications for treating asthma (oral ICS and ICS-LABA).

Preferred Drug List (PDL) therapeutic classes from the February 12, 2020 Drug Review Committee Meeting for the following: Long-acting opioids, Androgenic agents (topical and injectable), Antifungals (topical), Bladder Relaxants, Bronchodilators (Long-Acting Beta Agonists and Short-Acting Beta Agonists), Glucagon Agents, Intranasal Rhinitis Agents and Anti-inflammatory/Immunomodulator Ophthalmic Agents.

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I. ANNOUNCEMENTS

1. REMINDER: Morphine Milligram Equivalents (MME) Final Reduction

The final MME was reduced to **≤90 MME/day** on **November 14, 2018**. This is an additive edit for all opioid drug claims with overlapping days’ supply. The beneficiaries with certain cancer diagnoses in Medicaid medical diagnosis history are exempted from the MME edit. Incoming opioid claims that cause the total MME/day to exceed the existing limit of **≤ 90 MME/day** will *deny at point of sale* whether prescription is from same prescriber or different prescriber(s).

2. Electronic provider memo:

To reduce paper waste beginning April 2019, Arkansas Medicaid will no longer mail Pharmacy Program Provider Memos. An electronic message will be sent to all Medicaid enrolled prescribing providers and pharmacy providers as an alert message when the complete Provider Memo is posted on the Arkansas Medicaid Pharmacy Program website.

NOTE: To ensure you receive the notification email, please verify that your email is correct in the Arkansas Medicaid provider portal. Department of Human Services correspondence would also be included in this effort to reduce paper waste. To ensure that all correspondence is received, we ask that each provider verify that the provider portal has the correct email address used for your business communications.

The Arkansas Medicaid Pharmacy Program Provider Memos can be found at <https://medicaid.mmis.arkansas.gov/Provider/Provider.aspx>. To access the memos, select the OTHER LINKS drop-down menu in the upper-left corner of the screen, click MAGELLAN MEDICAID ADMINISTRATION, select the Administrator box, select the RESOURCES drop-down menu in the upper-right corner, click Documents, select the PHARMACY tab in the top row of tabs, and then click MEMORANDUMS. The Memo can also be found at: <https://arkansas.magellanrx.com/provider/documents/>. To access the memos, select the Pharmacy tab and then click Memorandums.

An added benefit of viewing the Medicaid Pharmacy Program Provider Memo online is the Search feature, which will allow a more accessible and efficient user experience. To use this feature, use the shortcut by pressing the Ctrl + F keys, enabling a keyword search. Starting with

the January 2018 memo, the online versions of the Provider Memos will also contain active hyperlinks in the Table of Contents. To activate these hyperlinks, open the Provider Memo, hover the mouse over the Table of Contents, press the Ctrl key until the mouse cursor (“hand”) appears, then place the cursor on the item desired and click the mouse. The hyperlink in the Table of Content will then redirect to the corresponding chapter of the Provider Memo.

3. Update on Truvada®, Descovy®, Viread® and Emtriva®

To remove any barriers to treatment of HIV or initiation of PrEP therapy, all previously required prior authorization criteria has been removed for Truvada®, Descovy®, Viread® and Emtriva®. Claims for these four medications will process at point-of-sale without a prior authorization. Quantity limits will still apply.

Prescribers can register as a PrEP provider on the Ready, Set, PrEP website at <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program>

EFFECTIVE April 1, 2020:

II. PREFERRED DRUGS LIST (PDL):

****Bolded medications have had a change in status.****

Testosterone Replacement Products

Preferred Agents with Criteria

- Testosterone Cypionate 100mg/ml injection
- Testosterone Cypionate 200mg/ml injection
- Testosterone Enanthate 200mg/ml injection
- **Testosterone gel pump (Generic Androgel®)**

Approval criteria

- Male
- Diagnosis of one of the following diagnoses in the previous 2 years:
 - o Hypospadias
 - o Klinefelter Syndrome
 - o Kallmann Syndrome
 - o Panhypopituitarism
 - o Prader-Willi Syndrome

Denial criteria

- Female
- Diagnosis of one of the following diagnoses in the previous 2 years:
 - o Decreased libido
 - o Impotence
 - o Any other sexual dysfunction diagnoses

Exceptions (Request through Manual Review Process)

Approve for women with diagnosis of breast cancer or hormone-responsive tumor in history

Nonpreferred Agents

- Androderm® patch
- Androgel® pump (Brand)

- Androgel® gel packet (Brand and generic)
- Aveed® injection
- Axiron® solution pump
- Depo-testosterone® injection (Brand)
- Fortesta® gel pump
- Natesto® nasal gel
- Testim® gel tube
- Vogelxo® gel tube, packet and pump
- Xyosted® injection

Long-Acting Opioids

Preferred Agents with Criteria

- Buprenorphine patch (Butrans)- **Brand Only**
- Morphine sulfate long-acting tablet (MS Contin)
- Tramadol ER Tablet (Ultram ER)

Nonpreferred Agents with Criteria

- Buprenorphine (Belbuca)
- Buprenorphine patch (Butrans)—**generic only**
- Fentanyl patch (Duragesic)
- Hydrocodone ER Capsule (Zohydro ER)
- Hydrocodone ER (Hysingla ER)
- Hydromorphone HCl extended-release tablet (Exalgo ER)
- Methadone HCl (Dolophine)
- Morphine sulfate extended-release capsule (Kadian)
- Morphine sulfate extended-release tablet (Morphabond ER, Arymo ER)
- Oxycodone extended-release tablet (Oxycontin)
- Oxycodone extended-release capsule (Xtampza ER)
- Oxymorphone HCl extended-release tablet (Opana ER)
- Tapentadol HCl extended-release tablet (Nucynta ER)
- Tramadol ER capsule (Conzip)
- Tramadol ER tablet (Ryzolt)

Bladder Relaxant Preparations

Preferred Agents

- Fesoterodine fumarate (Toviaz)
- Oxybutynin chloride 5mg/5ml Syrup, 5mg tablet (Ditropan)
- Oxybutynin chloride extended-release tablet (Ditropan XL Tablet)
- **Solifenacin succinate (Vesicare)—Generic only**

Nonpreferred Agents

- Darifenacin hydrobromide (Enablex)
- Flavoxate HCl (Urispas)
- Mirabegron extended-release (Myrbetriq)
- Oxybutynin chloride gel (Gelnique)
- Oxybutynin patch (Oxytrol)
- **Solifenacin succinate (Vesicare)—Brand**
- Tolterodine tartrate tablet (Detrol)
- Tolterodine tartrate extended-release capsule (Detrol LA)
- Trospium chloride extended-release (Sanctura XR)
- Trospium chloride immediate-release (Sanctura)

Long-Acting Beta Agonist

Preferred Agents with Criteria

- Salmeterol xiafoate disk with device (Serevent Diskus)

Approval criteria for Preferred agents with criteria

One of the following diagnoses or procedures:

- Anoxic brain injury (348.1)
- COPD
- Heart transplant (V421)
- Quadriplegic cerebral palsy (343.2)
- Respiratory insufficiency
 - 518.85 — Other pulmonary insufficiency, not elsewhere classified
 - 518.86 — Chronic respiratory failure
 - 518.87 — Acute and chronic respiratory failure
- Tracheostomy (Appendix B)
- Tracheomalacia congenital (748.3)

Nonpreferred Agents

- Arformoterol tartrate inhalation solution (Brovana)
- Formoterol fumarate inhaler (Foradil)
- Formoterol fumarate inhalation solution (Perforomist)
- Indacaterol maleate inhaler (Arcapta Neohaler)
- Olodaterol inhaler (Striverdi Respimat)

Short-Acting Beta Agonist

Preferred Agents

- ProAir HFA—Brand
- Proventil HFA—Brand
- Albuterol sulfate 2.5mg/0.5ml solution
- Albuterol sulfate 2.5mg/3ml solution
- Albuterol sulfate 5mg/ml solution
- **Albuterol sulfate 0.63mg/3ml solution**
- **Albuterol sulfate 1.25mg/3ml solution**

Nonpreferred Agents

- Albuterol sulfate HFA inhaler (Ventolin HFA Brand or Generic)
- Albuterol HFA (Generic for ProAir or Proventil)
- Albuterol sulfate HFA inhaler (ProAir RespiClick)
- Albuterol sulfate inhalation powder (ProAir Digihaler)
- Levalbuterol HCl inhalation solution (Xopenex inhalation solution)
- Levalbuterol tartrate HFA inhaler (Xopenex HFA)

Glucagon/Hypoglycemic Agents

Preferred Agents

- Glucagon 1mg injection
- Glucagon Emergency Kit 1mg injection
- Diazoxide Suspension (Proglycem)

Nonpreferred Agents

- Glucagon 0.5mg/0.1ml pre-filled syringe and Hypopen auto-injector (Gvoke)
- Glucagon 1mg/0.2ml pre-filled syringe and Hypopen auto-injector (Gvoke)
- Glucagon 3mg intranasal powder (Baqsimi)

Intranasal Rhinitis Agents

Preferred Agents

- Fluticasone propionate nasal spray (Flonase)
- Azelastine HCl nasal spray (Astelin, Astepro)
- Ipratropium 0.03% and 0.06% nasal spray

Nonpreferred Agents

- Azelastine/fluticasone nasal spray (Dymista)
- Beclomethasone dipropionate AQ nasal spray (Beconase AQ)
- Beclomethasone dipropionate nasal spray (Qnasl)
- Budesonide nasal spray
- Ciclesonide nasal spray (Omnaris, Zetonna)
- Flunisolide nasal spray
- Fluticasone propionate nasal spray (Xhance, Ticanase)
- Olopatadine HCl 6% nasal spray (Patanase)

Nonpreferred Agents with Criteria

- Mometasone furoate nasal spray (Nasonex)

Approval criteria for nonpreferred agents with criteria

- Approvable if the beneficiary is between 2 years through 3 years of age

Ophthalmic Immunomodulator Agents

Preferred Agents

- Cyclosporine 0.05% emulsion single dose (Restasis)

Nonpreferred Agents

- Cyclosporine 0.05% emulsion multidose (Restasis)
- Cyclosporine 0.09% solution (Cequa)
- Lifitegrast 5% solution (Xiidra)

Topical Antifungals

Preferred Agents

- Tolnaftate 1% topical cream OTC
- Tolnaftate 1% topical powder OTC
- Clotrimazole 1% Rx Cream
- Clotrimazole-Betamethasone Rx Cream
- Ketoconazole 2% Rx Shampoo
- Nystatin ointment, cream, powder
- **Nystatin/triamcinolone ointment**

Nonpreferred Agents

- Clotrimazole-Betamethasone Rx lotion
- Ciclopirox 0.77% cream, 1% shampoo (Ciclodan, Loprox)
- Econazole 1% cream
- Econazole 1% foam (Ecoza)
- Ketoconazole 2% cream, foam (Extina® Foam)

- Ketoconazole 2% gel (Xolegel)
- Luliconazole 1% cream (Luzu™)
- Oxiconazole 1% cream, lotion (Oxistat®)
- Sertaconazole 2% cream (Ertaczo®)
- Sulconazole 1% solution, cream (Exelderm®)
- Miconazole 0.25%/zinc oxide 15%/white petrolatum ointment 81.35% (Vusion® Ointment)
- Naftifine cream and gel (Naftin®)
- Butenafine 1% cream (Mentax®)
- Nystatin emollient cream (Pediaderm® AF)
- Nystatin/triamcinolone cream

Nonpreferred Agents for Onychomycosis

- ciclopirox 8% topical nail solution (Penlac® Nail Lacquer)
- efinaconazole 10% topical nail solution (Jublia®)
- tavaborole 5% topical nail solution (Kerydin®)

III. PRIOR AUTHORIZATION DRUG CRITERIA (NEW OR REVISED):

Effective April 15, 2020:

1. ENTRESTO® (sacubitril and valsartan) tablets

CRITERIA CHANGE:

- Remove manual review status and change status to preferred with criteria
- Make point-of-sale (POS) approval criteria
 - Diagnosis in Medicaid medical history in previous 2 years of congestive heart failure; **AND**
 - Recipient not pregnant meeting **BOTH** criteria below:
 - No billed diagnosis in Medicaid medical history of a pregnancy in the last 9 months; **AND**
 - No positive pregnancy test results billed in lab values in the last 9 months**If a pregnancy diagnosis is billed or a positive lab test is billed in the last 9 months, the system will look further for a delivery. If the recipient has delivered a baby and is no longer pregnant, the claim will process without a PA. If there is no indication of delivery, the claim will deny at POS and require a PA request to be submitted to the Magellan Help Desk. Fax PA request to 800-424-7895. **

Effective April 15, 2020:

2. SENSIPAR® (cinacalcet HCl) 30mg, 60mg and 90mg tab

APPROVAL CRITERIA:

Criterion 1: POS PA approval criteria for Treatment of Secondary Hyperparathyroidism (HPT) In Adult Patients with Chronic Kidney Disease (CKD) On Dialysis,

- Diagnosis in Medicaid medical history in previous 2 years of BOTH diagnoses codes for:
 - “Secondary HPT of renal origin” (ICD-10 code N25.81),**AND**
 - “ESRD CKD requiring Chronic Dialysis” (ICD-10 code N18.6 or Z99.2).

Manual review PA will be on a case-by-case basis if either diagnoses code is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Criterion 2: POS PA approval criteria for Treatment of Hypercalcemia in Adult Patients with Parathyroid Carcinoma.

- Diagnosis in Medicaid medical history in previous 2 years for:
 - “Cancer of the parathyroid gland” (ICD-10 code C75.0)
- AND**
- Diagnosis in Medicaid medical history in previous 2 years for: “Hypercalcemia” (ICD-10 code E83.52)
- OR**
- Hypercalcemia Level with calcium >10 mg/dL drawn in the previous 30 days

Manual review PA will be on a case-by-case basis if cancer diagnosis or documentation of hypercalcemia is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Criterion 3: POS approval criteria for Treatment of Hypercalcemia in Adult Patients with primary HPT for whom parathyroidectomy would be indicated based on serum calcium levels, but who are unable to undergo parathyroidectomy:

- Absence of a Parathyroidectomy in the Patient’s Medical History
 - NO Procedure Code for Parathyroidectomy in the past 2 years: (ICD-10 code Z90.89)
- AND**
- Diagnosis in Medicaid medical history in previous 2 years for: “Hypercalcemia” (ICD-10 code E83.52)
- OR**
- Hypercalcemia Level with calcium >10 mg/dL drawn in the previous 30 days

Manual review PA will be on a case-by-case basis if above criteria is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Effective April 15, 2020:

3. ERYTHROPOIESIS STIMULATING AGENTS

(Epogen® and Procrit®)

Aranesp® and Mircera® will remain nonpreferred and not be affected by this criterion change.

APPROVAL CRITERIA:

- Remove manual review status and change status to preferred with criteria on Procrit® and Epogen®. Aranesp® and Mircera® will continue to require a prior authorization submission.
- The Magellan system reviews lab results for the previous 30 days for a hemoglobin (Hgb) level. If a Hgb level is available and ≤ 10 g/dL, a claim will process at point-of-sale without a prior authorization.
- If hemoglobin level is not available in the Magellan system or the beneficiary does not meet the above lab requirement, a prior authorization request must be submitted to the Magellan Help Desk at 800-424-7895.

Effective immediately:

4. ESBRIET® (pirfenidone) 267mg capsule

INDICATION:

ESBRIET® is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Must be at least 18 years of age; **AND**
- Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung; **AND**
- Must be a non-smoker and prescriber must submit documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6ppm, carboxyhemoglobin (COHb) levels of <3% OR urine cotinine concentration <200ng/mL; **AND**
- Must not be pregnant; **AND**
- Prescriber must submit the following
 - Current chart notes with current weight
 - Specific dose requested (PA entered based on specific dose)
 - IPF staging classification
 - Liver Function Tests (LFTs)
 - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥50% and carbon monoxide diffusing capacity (%DLCO) of ≥35%
 - Results of high resolution CT scan of the lungs with documentation of Basal and peripheral predominance, Honeycombing (usually subpleural), or Reticular opacities, often in combination with traction bronchiectasis
 - Results of 6-minute walk test (6MWT) at baseline
 - Specific measurable goals for treatment outcomes

DENIAL CRITERIA:

- Does not meet approval criteria; **OR**
- Pregnant or breastfeeding; **OR**
- Currently smoking; **OR**
- Received lung transplant; **OR**
- Recent MI or stroke; **OR**
- Elevated liver enzymes with ALT and/or AST >3 X ULN with symptoms or hyperbilirubinemia OR ALT or AST >5 X ULN; **OR**
- Child Pugh C or ESRD; **OR**
- Requested dose >2403mg per day; **OR**
- Requested dose >801mg per day if taking concomitant strong CYP1A2 inhibitor; **OR**
- Requested dose >1602mg per day if taking concomitant moderate CYP1A2 inhibitor

CONTINUATION CRITERIA:

- Compliance on prescribed dose will be monitored; **AND**
- Patient should have a positive response for continuation; **AND**
- Prescriber should submit the requested dose along with the following for documentation of response to therapy:
 - Current chart notes with current weight
 - Current LFTs
 - Current PFTs
 - Current 6MWT
 - Current documentation of smoking status with either eCO, COHb or urine cotinine concentration
 - Dose requested (PA entered based on specific dose)

QUANTITY EDITS:

267mg—#279/31 days

801mg—#93/31 days

Effective immediately:

5. OFEV® (nintedanib) 100mg and 150mg capsules

INDICATIONS:

- Idiopathic Pulmonary Fibrosis (IPF)
- Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

APPROVAL CRITERIA: (No longer requires previous trial of Esbriet®)

- Manual review on a case-by-case basis; **AND**
- Must be at least 18 years of age; **AND**
- Must have one of the FDA approved indications—Idiopathic Pulmonary Fibrosis (IPF) or Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD); **AND**
- Must be a non-smoker; **AND**
- Must not be pregnant (provide pregnancy test results when applicable); **AND**
- Prescriber must submit the following for IPF patients; **AND**
 - Current chart notes
 - Specific dose requested (PA entered based on specific dose)
 - Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung
 - IPF staging classification
 - Liver Function Tests (LFTs)
 - Documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6ppm, carboxyhemoglobin (COHb) levels of <3% OR urine cotinine concentration <200ng/mL
 - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥50% and carbon monoxide diffusing capacity (%DLCO) 30%-79% of predicted
 - Results of high resolution CT scan of the lungs with documentation of Basal and peripheral predominance, Honeycombing (usually subpleural), or Reticular opacities, often in combination with traction bronchiectasis
 - Results of 6-minute walk test (6MWT) at baseline
 - Specific measurable goals for treatment outcomes
- Prescriber must submit the following for SSc-ILD patients; **AND**
 - Current chart notes
 - Specific dose requested (PA entered base on specific dose)
 - Chest high resolution computed tomography (HRCT) scan within the last 12 months with ≥10% fibrosis
 - Liver Function Tests (LFTs)
 - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥40% and carbon monoxide diffusing capacity (%DLCO) 30%-89% of predicted
 - Medical necessity over immunosuppressant therapy
 - Results of 6-minute walk test (6MWT) at baseline
 - Specific measurable goals for treatment outcomes

DENIAL CRITERIA:

- Does not meet approval criteria; **OR**
- Lung transplant; **OR**
- Pregnant or breastfeeding; **OR**
- Currently smoking; **OR**

- Elevated LFTs with ALT, AST or bilirubin >1.5 X ULN; **OR**
- Child Pugh B or C OR ESRD; **OR**
- Severe diarrhea, nausea or vomiting despite symptomatic treatment; **OR**
- Gastrointestinal perforation; **OR**
- Patient cannot tolerate minimum dose of 100mg twice daily

CONTINUATION CRITERIA:

- Compliance on prescribed dose will be monitored; **AND**
- Patient should have a positive response to the use for continuation; **AND**
- Prescriber should submit the requested dose along with the following for documentation of response to therapy:
 - Current chart notes with current weight
 - Current LFTs
 - Current PFTs
 - Current 6MWT
 - Current documentation of smoking status with either eCO, COHb or urine cotinine concentration
 - Dose requested (PA entered based on specific dose)

QUANTITY EDITS:

100mg--#62/31 days

150mg--#62/31 days

Effective May 13, 2020:

6. ASTHMA CRITERIA BASED ON GINA REPORT

Global Initiative for Asthma (GINA) report has been updated in 2019 following the routine twice-yearly review of the literature by the GINA Science Committee.

In summary, the key changes are:

- SABA-only treatment is no longer recommended for treatment of asthma in adults and adolescents.
- In mild asthma, treatment with daily low dose ICS is highly effective or as-needed low dose ICS-formoterol.
- In moderate-severe asthma, the preferred treatment is combination low dose ICS-LABA (specifically ICS-formoterol) as both maintenance and reliever.
- Off-label recommendations: the recommendations for long-term azithromycin in moderate-severe asthma; in mild asthma, for as-needed ICS-formoterol or ICS taken whenever SABA is taken (as combination or separate inhalers).
- Updated recommendations for initial asthma treatment, for stepping down treatment and for prevention of exercise-induced bronchoconstriction in line with evidence available with as-needed ICS-formoterol.
- Add-on low dose azithromycin is recommended as an option for patients with symptomatic asthma despite moderate-high dose ICS-LABA.
- High dose ICS-LABA treatment is now recommended only in Step 5.
- Maintenance oral corticosteroids are not a preferred treatment in Step 5.
- Children ages 6-11 years have separate treatment recommendations.

CRITERIA CHANGE:

Bronchodilators, Inhaled Combination Products (ICS-LABA)

Preferred Agents (ICS-LABA)

- Budesonide/Formoterol fumarate dihydride inhalation aerosol (Symbicort®)

Approval criteria for Symbicort®:

Criterion 1: COPD diagnosis in the past two years AND ≥ 40 years old

OR

Criterion 2: Paid drug claim in drug history for Advair Diskus®, Advair® HFA, Dulera®, or Symbicort® in the last six months

OR

Criterion 3: Asthma diagnosis in the past two years

Preferred agents with criteria (ICS-LABA)

- Mometasone furoate/Formoterol fumarate dihydride Inhalation Aerosol (Dulera®)
- Fluticasone propionate/Salmeterol inhalation powder (**Advair Diskus®**)– (**BRAND NAME ONLY**)

Approval criteria for preferred agents with criteria:

Criterion 1: COPD diagnosis in the past two years AND ≥ 40 years old.

OR

Criterion 2: Paid drug claim in drug history for Advair Diskus®, Advair® HFA, Dulera®, or Symbicort® in the last six months

OR

Criterion 3: One of the following criteria below:

- \geq Three inhaled corticosteroid claims in the last 120 days, OR
- \geq Three oral steroid claims in the last 120 days, OR
- Combination for \geq three claims (as defined below) in the last 120 days:
 - One Inhaled Corticosteroid + 2 Oral Steroids
 - Two Inhaled Corticosteroids + 1 Oral Steroids

Non-Preferred agents (ICS-LABA)

- Fluticasone furoate/Vilanterol inhalation powder (Breo® Ellipta®)
- Fluticasone propionate/Salmeterol inhalation aerosol (Advair® HFA)
- Fluticasone/Salmeterol (AirDuo)
- Fluticasone propionate/Salmeterol inhalation powder (Wixela®)
- Fluticasone propionate/ Salmeterol inhalation powder (generic)

Corticosteroids, Oral Inhaled

Preferred Agents (ICS only)

- Budesonide ampules for nebulizer* -**GENERIC ONLY**
- Fluticasone propionate HFA inhaler (Flovent HFA Inhaler)
- Mometasone furoate (**Asmanex Twisthaler**)

Nonpreferred agents (ICS only)

- Beclomethasone dipropionate inhaler (QVAR, QVAR REDIHALER)
- Budesonide inhaler (Pulmicort Flexhaler)
- Budesonide ampules for nebulizer (BRAND NAME PULMICORT RESPULES)
- Ciclesonide inhaler (Alvesco)
- Flunisolide inhaler (Aerospan)
- Fluticasone propionate disk with device (Flovent Diskus)
- Fluticasone propionate (Armonair Respiclick)
- Fluticasone furoate inhaler (Arnuity Ellipta)
- Mometasone furoate (Asmanex HFA)

Approval criteria for preferred agents with criteria

- Asthma diagnosis in the past two years.
- Claim will deny if there is a diagnosis for COPD in the past two years.

***Approval criteria for Budesonide Respules**

- < 4 years of age

Link to GINA Report 2019

<https://ginasthma.org/wp-content/uploads/2019/06/GINA-2019-main-report-June-2019-wms.pdf>

Effective April 1, 2020:

7. TEMODAR® (temozolomide) 5mg, 20mg, 100mg, 140mg, 180mg and 250mg capsule

INDICATION:

1.1 Newly Diagnosed Glioblastoma Multiforme

TEMODAR® (temozolomide) is indicated for the treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.

1.2 Refractory Anaplastic Astrocytoma

TEMODAR® is indicated for the treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- ≥ 18 years of age; **AND**
- Diagnosis consistent with the FDA approved; **AND**
- With diagnosis of Glioblastoma Multiforme, beneficiary must also receive radiotherapy in the initial treatment phase “Concomitant Phase”; **AND**
- Provide current chart notes; **AND**
- Provide the body surface area for dosing; **AND**
- If in concomitant phase for treatment of Glioblastoma, beneficiary must also receive Pneumocystis pneumonia (PCP) prophylaxis; **AND**
- Approval month-to-month due to continued monitoring of labs

DENIAL CRITERIA:

- Diagnosis not consistent with FDA approved indications; **OR**
- Beneficiary not tolerating the minimum dose of 100mg/m²; **OR**
- Pregnancy or breast-feeding; **OR**
- Severe hepatic impairment; **OR**
- Drug interaction with Valproic Acid—consider medical necessity

CONTINUATION CRITERIA:

- During concomitant phase, CBCs should be drawn at initiation and weekly during treatment. During maintenance phase, CBCs should be drawn on treatment Day 1 and on Day 22 of each cycle. LFTs should be drawn at baseline, midway through first cycle, prior to each subsequent cycle and 2-4 weeks after last dose; **AND**
- Current chart notes with response to therapy; **AND**
- Current body surface area and requested dose

QUANTITY EDITS:

No quantity edits because dosed based on Body Surface Area (BSA).

Effective immediately:

8. NOURIANZ™ (istradefylline) 20mg and 40mg tablets

INDICATION:

- NOURIANZ™ is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
- Off episodes is when the effects of the medication wears-off before a new dose can be taken resulting in recurrence of Parkinson's motor symptoms which include: resting tremor, bradykinesia (slowness of movement), rigidity, and postural instability.

APPROVAL CRITERIA:

- Must be at least 18 years of age; **AND**
- Provide current chart notes; **AND**
- Provide Liver Function Tests; **AND**
- Provide smoking status with average number of cigarettes per day; **AND**
- Should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; **AND**
- Must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting NOURIANZ™; **AND**
- Must be taking at least 3 doses of levodopa per day; **AND**
- NOURIANZ™ will be used in combination with levodopa/carbidopa; **AND**
- Must be experiencing at least 2 hours of OFF time per day; **AND**
- If taking other PD medications, patient must be on a stable dose for at least 4 weeks prior to starting NOURIANZ™ (although patients can be on levodopa/carbidopa without the concomitant use of other PD medications including COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine); **AND**
- Medical necessity over the increase in levodopa/carbidopa dose or changing to extended release formulations.

DENIAL CRITERIA:

- Currently taking strong CYP3A4 Inducers; **OR**
- Diagnosed with severe hepatic impairment (Child-Pugh C); **OR**
- Diagnosed with a major psychotic disorder; **OR**
- <2 hours per day of “OFF” time; **OR**
- Atypical parkinsonism or secondary parkinsonism variants; **OR**
- Pregnant or lactating females (Women of childbearing potential should be advised to use contraception during treatment with NOURIANZ™)

CONTINUATION CRITERIA:

- Chart notes indicating the patient has responded to therapy indicated by the reduction in “off” episodes characterized by tremor, sluggish movements, and gait disturbances and an increase in “on” episodes compared to baseline; **AND**
- Chart notes monitoring for the absence of adverse effects during treatment including new or worsening dyskinesia, development of impulse control disorders, hallucinations and other symptoms of psychosis; **AND**
- NOURIANZ™ will continue to be used in combination with levodopa/carbidopa

QUANTITY EDITS:

20mg tablets #31/31 days
40mg tablets #31/31 days

Effective immediately:

9. EGATEN® (triclabendazole) 250mg tablet

No pricing data has been provided by the manufacturer so Egaten® is not available through Medicaid. When the manufacturer does submit pricing information, the following criteria will be in place.

INDICATION:

EGATEN® is an anthelmintic indicated for the treatment of fascioliasis in patients 6 years of age and older.

APPROVAL CRITERIA:

- Patient must be at least 6 years old; **AND**
- The infection must be confirmed by a diagnostic or laboratory test (documented by the presence of parasite eggs in the stool or documented worm-specific antibodies in serum samples)

DENIAL CRITERIA:

- Patients with known hypersensitivity to triclabendazole or other benzimidazole derivatives; **OR**
- Pregnant or lactating females; **OR**
- Fascioliasis is not confirmed

CONTINUATION CRITERIA:

This drug is indicated for short-term acute use

QUANTITY EDITS:

No specific quantity limits except claim approved for 2 doses only based on weight

Effective immediately:

10. TRIKAFTA™ (elexacaftor, tezacaftor and ivacaftor) kit

INDICATION:

TRIKAFTA™ is a combination of ivacaftor, a CFTR potentiator, tezacaftor, a CFTR corrector, and elexacaftor, known as a next generation corrector, indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene.

APPROVAL CRITERIA:

- Must be at least 12 years old; **AND**
- Must have a diagnosis of Cystic Fibrosis; **AND**
- Must have at least one (1) F508del mutation in the CFTR gene; **AND**
- Provide current chart notes with documentation of previous therapies; **AND**
- Provide current PFTs; **AND**
- If the beneficiary failed therapy with Kalydeco®, Orkambi® OR Symdeko® and is requesting a switch to Trikafta™, submit chart notes with documentation of failure; **AND**
- Beneficiary is adherent to standard of care therapies for treating CF; **AND**
- Baseline assessments of liver function tests (ALT, AST, and bilirubin) prior to initiating Trikafta™; **AND**
- For the initial PA approval and continuation reviews, the liver function lab results for ALT or AST must be less than 3 times the upper limit of normal (ULN) with bilirubin elevations less than 2 times the ULN, OR the liver function lab results for ALT or AST must be less than 5 times the upper limit of normal without bilirubin elevation; **AND**
- Baseline eye exams in younger patients between the age of 12 and 17 prior to initiating Trikafta™; **AND**
- Must be a non-smoker and prescriber must submit documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6ppm, carboxyhemoglobin (COHb) levels of <3% OR urine cotinine concentration <200ng/mL; **AND**
- Documentation of dosage change if requires concomitant moderate or strong CYP3A Inhibitors; **AND**
- Initial approval will be for 3 months. After 6 months of Trikafta™ with documentation of stabilization or improvement, PAs may be entered for 6 months.

DENIAL CRITERIA:

- Severe hepatic impairment (Child-Pugh C); **OR**
- Beneficiary does not have a diagnosis of Cystic Fibrosis; **OR**
- Does not meet approval criteria; **OR**
- Current colonization with organisms associated with a more rapid decline in pulmonary status (i.e. Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus); **OR**
- <12 years of age; **OR**
- Pregnancy or breastfeeding; **OR**
- Tobacco use; **OR**
- Concomitant use of strong CYP3A inducers

CONTINUATION CRITERIA:

- Current chart notes with documentation of clinical response (after 6 months of treatment) and prescriber must submit documentation to substantiate the following:
 - o Stabilization or improvement in lung function (FEV1);
 - o Stabilization or improvement in weight gain;
 - o Reduction in exacerbations/hospitalizations.
- Lab results with recent assessment of liver function tests (ALT, AST, CPK, and bilirubin) within 3 months since starting treatment (LFTs should be done every 3 months within the first year of starting Trikafta™ and then yearly afterwards); **AND**
- Beneficiary remains a non-smoker

QUANTITY EDITS: #84/28 days

Effective April 1, 2020:

11. FEIBA (anti-inhibitor coagulant) 500, 1000 and 2500 unit kits

INDICATION:

- FEIBA (Factor Eight Inhibitor Bypassing Activity) is an Anti-Inhibitor Coagulant Complex indicated for use in hemophilia A and B patients with inhibitors for:
 - Control and prevention of bleeding episodes
 - Perioperative management
 - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

FEIBA is not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to factor VIII or factor IX.

APPROVAL CRITERIA:

- Diagnosis of congenital factor VIII or IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has high Factor VIII or factor IX titer inhibitors (≥ 5 Bethesda Units); **AND**
- Used as treatment in at least one of the following:
 - Control and prevention of bleeding episodes; **OR**
 - Perioperative management; **OR**
 - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Patient has a documented trial of Immune Tolerance Induction (ITI) therapy and emicizumab-kxwh (Hemlibra) (FEIBA may be taken as breakthrough for patients taking emicizumab)- **Hemophilia A only; AND**
- Patient has a documented trial and failure of combination of Immune Tolerance Induction (ITI) therapy and highly immunosuppressive regimens – **Hemophilia B only (see explanation below**); AND**
- If doses above 100 units/kg or daily doses of 200 units/kg are required, provide the treatment plan to monitor for Disseminated Intravascular Coagulation (DIC) or signs of ischemia and thromboembolic events; **AND**
- Chart notes with history of bleeds and treatment for the last 24 weeks, current labs and current weight for dosing; **AND**
- Provide requested dose as PA will be entered for specific dosing requirements

DENIAL CRITERIA:

- Documented previous severe allergic reaction to FEIBA or tendency to develop allergic reactions or hypersensitivity to any human plasma-derived product; **OR**
- No medical necessity provided over ITI therapy or emicizumab for Hemophilia A patients (does not preclude patient from getting FEIBA for breakthrough while taking preventative emicizumab); **OR**
- Diagnosis of Disseminated Intravascular Coagulation (DIC); **OR**
- Acute thrombosis or embolism (such as angina, myocardial infarction, heart attack or stroke); **OR**
- Pregnant or breastfeeding women

Use of FEIBA during pregnancy or breastfeeding is not recommended, due to insufficient information being available. FEIBA should be administered to pregnant women only if clearly needed

CONTINUATION CRITERIA:

- Record of clinical response to treatment (evidence of hemostasis) with chart notes and appropriate labs; **AND**
- Absence of unacceptable toxicity from the drug (thromboembolic events which includes venous thrombosis, pulmonary embolism, myocardial infarction, and stroke)

QUANTITY EDITS:

Quantity entered of time of PA; no specific quantity edits

NOTE: FEIBA may be used in conjunction with Hemlibra® for control of bleeding episodes.

Effective April 1, 2020:

12. NOVOSEVEN RT (coagulation factor VIIa-recombinant) kit

INDICATION:

NovoSeven RT is a coagulation factor indicated for:

- Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets
- Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia

APPROVAL CRITERIA:

- Chart notes with history of bleeds and treatment for the last 24 weeks, current labs and current weight for dosing; **AND**
- Provide requested dose as PA will be entered for specific dosing requirements

Hemophilia A or B with Inhibitors

- Diagnosis of congenital or acquired hemophilia A or B with inhibitors confirmed by blood coagulation testing; **AND**
- Used for treatment of at least one of the following:
 - Control and prevention acute of bleeding episodes; **OR**
 - Perioperative management; **AND**
- Patient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy and emicizumab-kxwh (Hemlibra) (NovoSeven may be taken as breakthrough for patients taking emicizumab) - **Hemophilia A only**
- Patient has a documented trial and failure of combination of Immune Tolerance Induction (ITI) therapy and highly immunosuppressive regimens – **Hemophilia B only**

Congenital Factor VII Deficiency

- Diagnosis of congenital factor VII deficiency confirmed by blood coagulation testing; **AND**
- Documentation of prothrombin time and factor VII coagulant activity prior to administration as baseline; **AND**
- Used for treatment of at least one of the following:
 - Control and prevention of acute bleeding episodes; **OR**
 - Perioperative management

Glanzmann's Thrombasthenia

- Diagnosis of Glanzmann's thrombasthenia; **AND**
- Condition is refractory to platelet transfusions; **AND**
- Used for the treatment of one of the following:
 - Control and prevention of bleeding episodes; **OR**
 - Perioperative management

Acquired Hemophilia

- Diagnosis of Acquired Hemophilia; **AND**
- Used for the treatment of one of the following:
 - Control and prevention of bleeding episodes; **OR**
 - Perioperative management

DENIAL CRITERIA:

- Known hypersensitivity to NovoSeven or any of the components of NovoSeven; **OR**
- Hypersensitivity to mouse, hamster, or bovine proteins; **OR**
- Continued use of activated prothrombin complex concentrates (aPCC); **OR**

- Continued use of coagulation factor VIII

CONTINUATION CRITERIA:

- Record of clinical response to treatment (evidence of hemostasis); **AND**
- Absence of unacceptable toxicity from the drug (thromboembolic events which includes venous thrombosis, pulmonary embolism, myocardial infarction, and stroke); **AND**
- Factor VII clotting activity – **for Congenital Factor VII Deficiency**

QUANTITY EDITS:

Quantity entered of time of PA; no specific quantity edits

Effective immediately:

13. PRETOMANID 200mg tablet

INDICATION:

Pretomanid Tablet is indicated, as part of a combination regimen with Sirturo® (bedaquiline) and Zyvox® (linezolid) for the treatment of adults with pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB). Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.

Limitations of Use:

Pretomanid Tablets are not indicated in patients with the following conditions:

- Drug-sensitive (DS) tuberculosis
- Latent infection due to Mycobacterium tuberculosis.
- Extra-pulmonary infection due to Mycobacterium tuberculosis.
- MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy.

APPROVAL CRITERIA: (NOTE: Arkansas Department of Health reviews all TB therapy and may make a recommendation outside of this criterion.)

- Diagnosed with pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); **AND**
- Age ≥ 18 years; **AND**
- Taking Sirturo® (bedaquiline) and Zyvox (linezolid) concomitantly unless otherwise contraindicated; **AND**
- Provide baseline ECG if also taking other medications that prolong QT interval; **AND**
- Request must have been reviewed and submitted by the Arkansas Department of Health's TB Control Program. If a prescriber outside of the Department of Health requests this medication, the TB control program must be notified.

DENIAL CRITERIA:

- Does not meet FDA approved diagnosis; **OR**
- Clinically significant ventricular arrhythmia or QTcF interval >500ms; **OR**
- Coadministration of moderate or strong CYP3A4 inducers

CONTINUATION CRITERIA:

- Positive cultures to continue beyond week 26; **AND**
- Current chart notes

QUANTITY EDITS:

#31/31 days

Effective immediately:

14. NAYZILAM® (midazolam) spray

INDICATION:

NAYZILAM is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

NOTE: Nayzilam® will not be included in opioid and benzodiazepine poisoning criteria.

APPROVAL CRITERIA:

- Diagnosis of partial or generalized epilepsy; **AND**
- Must be at least 12 years old; **AND**
- Provide current chart notes and current labs to monitor renal function; **AND**
- Experiencing stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures, recurrent seizures); **AND**
- Currently on a stable regimen of antiepileptic drugs (AEDs); **AND**
- Medical necessity over the use of Diazepam Gel; **AND**
- Must be ordered by a neurologist

DENIAL CRITERIA:

- Has a neurological disorder that is likely to progress in the next year; **OR**
- Has severe chronic cardio-respiratory disease; **OR**
- Has a history of their stereotypical seizure cluster progressing to status epilepticus within the last 2 years; **OR**
- Has a history of acute narrow-angle glaucoma; **OR**
- Taking moderate or strong CYP3A4 inhibitors; **OR**
- Pregnancy or breastfeeding

CONTINUATION CRITERIA:

- Patient is responding positively to therapy (termination of seizure(s) within 10 minutes after drug administration, and no recurrence of seizure(s) for up to 6 hours after drug administration); **AND**
- Patient is not exceeding maximum allowable dose of 2 doses per single episode; **AND**
- Patient profile will be reviewed for utilization. If filling monthly, maintenance medication may need to be adjusted; **AND**
- Provide current chart notes with overall response to therapy

QUANTITY EDITS:

Max of 5 packs (10 doses) per month

Effective immediately:

15. OXBRYTA™ (voxelotor) 500mg tablet

INDICATION:

OXBRYTA™ is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older.

This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Must be at least 12 years old; **AND**
- Must have a diagnosis of Sickle Cell Disease; **AND**
- Must not be pregnant; **AND**
- Has had from 1 to 10 vasoocclusive crisis (VOC) events in the last 12 months; **AND**
- Must have hemoglobin (Hb) level ≥ 5.5 to ≤ 10.5 g/dL; **AND**
- Prescriber should submit the following:
 - Chart notes
 - History of Sickle Cell treatment including VOC events and hospitalization in the last 12 months
 - Documentation of Hydroxyurea usage (previous usage is required unless contraindicated)
 - Current labs including CBC and LFTs

DENIAL CRITERIA:

- Does not have a diagnosis of Sickle Cell Disease; **OR**
- Received an RBC transfusion in the last 60 days or erythropoietin within the last 28 days; **OR**
- Pregnancy or breastfeeding; **OR**
- Severe hepatic impairment

CONTINUATION CRITERIA:

- Compliance on therapy; **AND**
- Documentation of positive response to therapy including an improvement in Hb level AND decrease in VOC events; **AND**
- Prescriber should submit the following:
 - Current chart notes
 - Current labs including CBC and LFTs

QUANTITY EDITS:

#90/30 days

FRIENDLY REMINDERS:

1. **Effective March 1, 2019**, Arkansas Medicaid implemented **PASSE (Provider-Led Arkansas Shared Savings Entity)**, a new Medicaid program to address the needs of individuals who have intensive behavioral health and intellectual and developmental disabilities service needs. The PASSE organizations administer all medical needs and all pharmacy prescription drug needs for all PASSE members. **Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member.** For more information about PASSE, please refer to the website: <https://humanservices.arkansas.gov/about-dhs/dms/passe>. For questions about each PASSE organization, please refer to this website for contact information: <https://humanservices.arkansas.gov/about-dhs/dms/passe/contact-us>
2. **MAT (Medication Assisted Treatment) with Buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40*: **“Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care.** As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. **Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities.** In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the OTP setting, they must attest to their capacity to refer such

patients for appropriate counseling and other nonpharmacological therapies.”

<http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf>

Per ASAM National Practice Guideline, in Part 5: Buprenorphine, Summary of Recommendations, # (5)

“Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder.” <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

3. **Chronic Pain Patients Who Do Not Need Treatment for Addiction:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40*: “Patients who need treatment for pain but not for addiction should be treated within the context of their regular medical or surgical setting. They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids during their medical treatment.” Substance Abuse and Mental Health Services Administration ([SAMHSA](http://www.samhsa.gov)) Center for Substance Abuse Treatment. <http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf>
4. **INCARCERATED PERSONS:**
*The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid beneficiaries who, **on the date the prescription is filled, is incarcerated in a correctional or holding facility, including juvenile correctional facilities,** and are detained pending disposition of charges, or are held under court order as material witnesses. **If medications are requested for incarcerated Medicaid beneficiaries, including beneficiaries in a juvenile correctional facility, the medications cannot be billed to Medicaid Pharmacy Program and are SUBJECT TO RECOUPMENT if billed to Medicaid.** Pharmacists should contact the correctional facility regarding the facility’s reimbursement procedures for the requested medications.*
5. **Suboxone Film (buprenorphine/naloxone) once daily dosing:** as stated in the Suboxone Film package insert, the FDA approved dose for treating opioid addiction is **prescribing the total daily dose as one single daily dose.** “After treatment induction and stabilization, the maintenance dose of SUBOXONE sublingual film is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response. The recommended target dosage of SUBOXONE sublingual film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day **as a single daily dose.** Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage.”

Per ASAM National Practice Guidelines, the bold and italics were added for emphasis, but the following statement is pulled from the “At Induction” section of “Part 5: Buprenorphine”, under Dosing, “Once it has been established that the initial dose is well tolerated, the buprenorphine dose can be increased fairly rapidly to a **dose that provides stable effects for 24 hours and is clinically effective**”.
<https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>
6. **CIRCUMVENTING MEDICAID LIMITS FOR OPIOIDS AND BENZODIAZEPINES:**
Beneficiaries who pay *cash* for opioids to avoid Medicaid dose and quantity limits *or* pay cash *in addition to* the opioids paid for by Medicaid, result in a much higher daily MME than what is calculated in the Medicaid system edits, are above the CDC recommendations, and could *put the patient at risk for overdose*. **According to the CDC, the number of Arkansas deaths due to drug overdose increased 10.2% from December 2016 to December 2017.**
7. **REGARDING MANUAL REVIEW PA REQUESTS:** Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an *exception* to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the PDL, are all reviewed on a *case-by-case basis* through a manual review process. All manual review requests for prior authorization *require, at a minimum, the prescriber to provide a letter explaining the medical necessity* for the requested drug *along with all written documentation to substantiate the medical necessity*, e.g., chart notes, pharmacy printouts for cash, printout of private insurance paid drugs, lab results, etc. **Please note that starting the requested drug, including long-acting injectable antipsychotic agents, through either inpatient use, the use of office “samples”, or by any other means, prior to a Prior Authorization request being reviewed and approved by the Medicaid Pharmacy Program does not necessitate Medicaid Pharmacy Program approval of the requested drug.**

8. **“CLAIM EDITS”** referred to in this memo include quantity edits, cumulative quantity edits, monthly quantity edits, age edits, gender edits, accumulation quantity edits, and daily dose edits.
9. **CHANGE IN MANUAL REVIEW PA FOR THE AGE OF CHILDREN PRESCRIBED ANTIPSYCHOTIC AGENTS, EFFECTIVE JANUARY 1, 2017:** Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) **for all new starts on an antipsychotic agent, including a change in the chemical entity for children currently on an antipsychotic agent.** All documentation, chart notes, signed informed consent, and required lab work must be submitted and the manual review will be performed by the Medicaid Pharmacy Program board certified child & adolescent psychiatrist.
10. **SECOND GENERATION ANTIDEPRESSANTS, TRAZODONE, AND TRICYCLIC ANTIDEPRESSANTS PRESCRIBED TO CHILDREN ≤ 3 YEARS OF AGE, EFFECTIVE MARCH 8, 2017:** The current point of sale (POS) prior approval (PA) criteria for the second-generation antidepressants, including Trazodone, were developed based on utilization for adults, and the minimum and maximum therapeutic doses were based on adult doses. ***Second Generation Antidepressants, Trazodone, or Tricyclic Antidepressants for Children ≤ 3 years of age will require manual review prior approval (PA) by the Medicaid Pharmacy Program child psychiatrist.*** The prescriber must submit the request in writing, explain the medical necessity for the child to receive the drug requested, and include chart notes and any other documentation that will substantiate the request and the dose. Each request will be reviewed on a case-by-case basis.
11. **REGARDING EMERGENCY OVERRIDE:** In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense *up to* a five-day supply of a drug that requires prior authorization e.g., a drug that requires a clinical PA or requires a PA for a non-preferred drug. **This provision applies *only in an emergency* when the MMA Prescription Drug Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC beneficiaries and once per 60 days per drug class for LTC beneficiaries.

To submit a claim using this emergency provision, the pharmacy provider must submit “03” in the Level of Service (418-DI) field. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website, <https://arkansas.magellanrx.com/provider/documents/>.

12. **HARD EDIT ON EARLY REFILL FOR CONTROLLED AND NON-CONTROLLED DRUGS:** The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days’ supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days’ supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days’ supply elapsed will require a manual review PA and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits or an approved PA must be in the system for the beneficiary for the higher dose or an early refill PA will *not* be approved.
13. **REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:** Beginning February 16, 2016, when a pharmacy refills a prescription claim early (e.g., for a non-controlled drug or a controlled drug 1 day early to 7 days early without a PA or sooner with a PA), the Medicaid system began adding together the accumulated “early days” filled. Each prescription is tracked by the Generic Sequence Number (GSN), which means the drug claim is the same generic name, same strength, and same dosage form, rather than tracking by prescription number or NDC. Once the beneficiary has accumulated an “extra” 15 days’ supply for that GSN, any incoming claim that is early will reject at point of sale. For example, if the prescription drug claim was for a 30-day supply and was filled 7 days early on February 16, 2016, and filled 7 days early again on March 10, 2016, the beneficiary can only refill the prescription 1 day early on the next refill date, which would be April 8, 2016 (1 day early). The accumulation edit is set so that the beneficiary cannot accumulate *more than an extra* 15 days’ supply early during a 180-day period. In this example, the drug claim cannot be filled early again until *after* August 14, 2016, which is 180 days from the February 16, 2016 date.

Effective August 8, 2018, the RTS logic with Early Refill Accumulation Limited edit was revised for the **non-controlled drugs** which now **allow an accumulation of 12 days’ supply during the previous 180-day period.**

Effective February 14, 2018, the RTS logic with Early Refill Accumulation Limit edit is **revised for the controlled drugs**. The revised edit for controlled drugs will only allow an extra 7-days' supply accumulation through early fills in previous 180-day period rather than an accumulation of an extra 15-days' supply. The RTS logic with Early Refill Accumulation Limit edit for non-controlled drugs will remain as is. Early refills for both controlled drugs and non-controlled drugs will continue to be monitored and may be adjusted in the future to reduce misuse.

14. **REVERSE AND CREDIT MEDICAID PRESCRIPTIONS NOT PROVIDED TO BENEFICIARY:** Pharmacies are required to reverse and credit back to Medicaid original prescriptions and refills if the medication was not provided to the beneficiary. Pharmacies should reverse and credit Medicaid within 14 days of the date of service for any prescription that was not provided to the beneficiary. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.
15. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN < 18 YEARS OF AGE have an ongoing requirement for labs** for metabolic monitoring every 6 months. When any provider sends a patient, who is less than 18 years of age for the required metabolic labs for the antipsychotic agents, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.
16. **INFORMED CONSENT FORM FOR ANTIPSYCHOTIC AGENT PA FOR CHILDREN < 18 YEARS OF AGE:** For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form has been updated (v072914) and is posted on the Medicaid website. As the form is updated and posted on the Medicaid website, providers are required to use the most current form. Effective, Dec. 10, 2013, the old versions will no longer be accepted.
17. **FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS: Effective JULY 1, 2016,** Providers requesting a Prior Authorization (PA) for a drug on the PDL or calling to request a Prior Authorization (PA) for an antipsychotic medication should call the **PDL PA Call Center at 1-800-424-7895. The PDL FAX number is: 1-800- 424-5739.** Please fax a letter explaining the medical necessity and include any supporting documentation, the beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.
18. **FOR NON-PDL DRUGS AND FOR NON-ANTIPSYCHOTIC DRUG REQUESTS:** Providers requesting a Prior Authorization (PA) should call the Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895. For Prior Authorization (PA) requests requiring manual review, you may fax your request to the MMA Help Desk Fax at 1-800-424-7976. Please include any supporting documentation for the request with the fax, and include beneficiary ID number, beneficiary name, and physician Medicaid provider ID with your request. An approval, denial, or request for additional information will be returned by the close of business the following business day.
19. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID BENEFICIARIES WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that beneficiary can be billed using the beneficiary's Medicaid ID. If medications are needed to treat remaining family members, each prescription must be billed accordingly to each family member's Medicaid ID number. Sanctions may be imposed against a provider for engaging in conduct that defrauds or abuses the Medicaid program. This could include billing a child's medication to a parent's Medicaid ID number and vice-versa.
20. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:** AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to \$9 for Brand Drugs and \$10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website: <https://arkansas.magellanrx.com/provider/documents/> A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website:

https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

21. **AR MEDICAID PHARMACY PROGRAM IS ON FACEBOOK:** The Arkansas Medicaid Pharmacy Program is now on Facebook. Please join our group page titled “AR Medicaid Pharmacy Provider Help Group”. This is a closed group for providers of Arkansas Medicaid services or those who work for a provider of Arkansas Medicaid services and join requests will be verified. The group is administered by a State of Arkansas employee and a Magellan Medicaid Administration employee on his/her own time. The purpose of the group page is to help the provider community with any issues that involve billing or prescribing covered outpatient drugs through the Arkansas Medicaid Pharmacy Program. We will not disclose any PHI and will delete any posts that contain PHI. Want to know what criteria is needed for a drug? Don't know who to call to handle your issue? Just post your questions and we will answer.

This advance notice is to provide you the opportunity to contact, counsel, and change patients' prescriptions.

If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at 501-320-6429.

If you have questions regarding this transmittal, or you need this material in an alternative format such as large print, please contact the Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895. For copies of past Remittance Advices (RA) or Arkansas Medicaid Provider Manuals (including update transmittals), please contact the HP Enterprise Services Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.