ARKANSAS DEPARTMENT OF HUMAN SERVICES

P.O. Box 1437, Slot S415 · Little Rock, AR 72203-1437
Phone: 501-683-4120 · Fax: 1-800-424-5851

MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: November 24, 2021

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board October 20, 2021 meeting for the following:**
Manual review criteria for: Hidradenitis Suppurativa, palivizumab (Synagis®), ibrexafungerp (Brexafemme®), belumosudil (Rezurock™), odevixibat (Bylvay™), rifamycin (Aemcolo™), and belzutifan (Welireg™)

Point-of-Sale edits for: Immunoglobulin (IVIG and SCIG), quantity edits for antiepileptic medications, dose optimization for multiple drug classes (blood pressure, diabetes, cholesterol, and blood modifiers)

Preferred Drug List (PDL) therapeutic classes: (November 10, 2021 Drug Review Committee meeting) Antiparkinson's disease, beta blockers, neuropathic pain agents, and sedative hypnotics (benzodiazepine and non-benzodiazepine)

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I. ANNOUNCEMENTS

A. CLARIFICATION FOR ICS-LABA CRITERIA

POINT-OF-SALE APPROVAL CRITERIA for Symbicort® and Dulera®:
****NOTE** Only Symbicort® and Dulera® may be used for SMART therapy.**

For Criterion 1: COPD diagnosis in the past two years **AND** ≥ 40 years old
OR
For Criterion 2: Paid drug claim in drug history for Advair Diskus®, Advair® HFA, Dulera®, or Symbicort® in the last six months
OR
For Criterion 3:
- Age ≥ 4 years of age; **AND**
- Asthma diagnosis billed in the past 2 years

OR
For Criterion 4:
- Age ≥ 4 years old; **AND**
- One of the following criteria below:
  - ≥ Three inhaled corticosteroid claims in the last 120 days; **OR**
  - ≥ Three oral steroid claims in the last 120 days; **OR**
  - Combination for ≥ three claims (as defined below) in the last 120 days:
    - o One Inhaled Corticosteroid + 2 Oral Steroids
    - o Two Inhaled Corticosteroids + 1 Oral Steroids

QUANTITY EDITS:
Symbicort®--#2 inhalers per month for 120 actuation size
If the recipient needs > 8 puffs per day, a PA can be submitted to approve an additional inhaler.

Dulera®–#2 inhalers per month

POINT-OF-SALE APPROVAL CRITERIA for Advair Diskus®
****NOTE** Advair Diskus® is not recommended for SMART therapy and should not be used for rescue.**

For Criterion 1: COPD diagnosis in the past two years **AND** ≥ 40 years old
OR
For Criterion 2: Paid drug claim in drug history for Advair Diskus®, Advair® HFA, Dulera®, or Symbicort® in the last six months
OR
For Criterion 3:
- Age ≥ 4 years of age; **AND**
- Asthma diagnosis billed in the past 2 years

OR
For Criterion 4:
- Age ≥ 4 years old; **AND**
- One of the following criteria below:
  - ≥ Three inhaled corticosteroid claims in the last 120 days; **OR**
  - ≥ Three oral steroid claims in the last 120 days; **OR**
  - Combination for ≥ three claims (as defined below) in the last 120 days:
    - o One Inhaled Corticosteroid + 2 Oral Steroids
    - o Two Inhaled Corticosteroids + 1 Oral Steroids

QUANTITY EDITS:
Advair Diskus®--#1 inhaler per month

B. POLYPHARMACY EDITS

Effective December 1, 2021, concomitant fills for an opioid and benzodiazepine will prompt a drug-to-drug interaction message at point-of-sale requiring the pharmacy to override the DUR rejection with approved DUR codes. PA restrictions will remain in place.

The following codes can be used to override the DUE rejection.
Response for Service Code: Drug-Drug (DD)
Professional Service Code: M0, P0, or R0
Result of Service: 1A, 1B, 1C, 1D, 1E, 1F, 1G, 2A, or 2B

C. COVID-19 VACCINATION UPDATES

***Review the Department of Human Services COVID response page for updates to any new billing guidance. Updates for Providers - Arkansas Department of Human Services**

D. MEDICAID SLOT UPDATE

Act 758 is scheduled to go into effect Jan. 1, 2022. All adult Medicaid clients age 21 and older who are in the fee-for-service Medicaid program will be able to get up to six (6) prescriptions paid for by Medicaid, with five (5) classes of medication that will not count toward that limit. Extension of benefits will no longer be needed. The previous exceptions that do not count towards the limit still apply, which are birth control pills, contraceptives, medications used to treat opioid use disorder, and smoking cessation products. The new medication types that do not count toward the limit of six (6) are:

- High blood pressure agents
- High cholesterol agents
- Bleeding disorder agents
- Diabetes drugs
- Inhalers for breathing disorders

The previous prescription limit of five (5) times filled or not allowed to be filled beyond six (6) months after the date of the original issue is also no longer in effect. All prescription refill allowances will be in accordance with State and Federal guidelines.

EFFECTIVE JANUARY 1, 2022:

II. PREFERRED DRUG LIST (PDL):

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

1. ANTIPARKINSON'S AGENTS (new PDL class)

Preferred agents

- Amantadine capsule (generic for Symmetrel)
- Amantadine syrup (generic for Symmetrel)
- Benztropine (generic for Cogentin)
- Carbidopa/Levodopa ER (generic for Sinemet CR)
- Carbidopa/Levodopa (generic for Sinemet)
- Pramipexole (generic for Mirapex)
- Ropinirole (generic for Requip)
- Trihexyphenidyl (generic for Artane)
- Trihexyphenidyl Elixir (generic for Artane)

Nonpreferred agents

- Amantadine tablet (generic for Symmetrel)
- Apokyn (apomorphine)
- Azilect (rasagiline)
- Bromocriptine (generic for Parlodel)
- Carbidopa (generic for Lodosyn)
- Carbidopa/Levodopa ODT (generic for Parcopa)
- Carbidopa/Levodopa/Entacapone (generic for Stalevo)
- Comtan (entacapone)
- Duopa suspension (carbidopa/levodopa)
- Entacapone (generic for Comtan)
- Gocovri capsule (amantadine)
- Lodosyn (carbidopa)
- Mirapex ER (pramipexole ER)
- Neupro patch (rotigotine)
- Osmolex ER tablet (amantadine)
- Parlodel (bromocriptine)
- Pramipexole ER (generic for Mirapex ER)
- Rasagiline (generic for Azilect)
- Ropinirole ER (generic for Requip XL)
- Rytary (carbidopa/levodopa ER)
- Selegiline capsule (generic for Eldepryl)
- Selegiline tablet (generic for Zelapar)
- Sinemet (carbidopa/levodopa)
- Stalevo (carbidopa/levodopa/entacapone)
- Tasmar (tolcapone)
- Tolcapone (generic for Tasmar)
- Xadago (safinamide)
- Zelapar (selegiline)

Nonpreferred agents with criteria

- Inbrija (levodopa)
- Kynmobi (apomorphine)
- Nourianz (istradefylline)
- Ongentys (opicapone)

2. BETA BLOCKERS

Preferred agents

- Acebutolol HCl (generic for Sectral)
- Atenolol (generic for Tenormin)
- Atenolol/Chlorthalidone (generic for Tenoretic)
- Bisoprolol fumarate (generic for Zebeta)
- Bisoprolol/HCTZ (generic for Ziac)

- **Bystolic (Nebivolol) BRAND NAME ONLY**
- Carvedilol tablet (generic for Coreg)
- Labetalol HCl (generic for Normodyne)
- Metoprolol succinate extended-release (generic for Toprol XL)
- Metoprolol tartrate (generic for Lopressor)
- Propranolol HCl immediate-release (generic for Inderal)
- Sotalol (generic for Betapace)

Nonpreferred agents

- Betapace (sotalol)
- **Betaxolol HCl (generic for Kerlone)**
- Carvedilol phosphate capsule (Coreg CR)
- Coreg (carvedilol)
- Coreg CR (carvedilol CR)
- Corgard (nadolol)
- Hemangeol (propranolol solution)
- Inderal LA (propranolol ER)
- **Kapspargo sprinkle (metoprolol succinate)**
- Lopressor (metoprolol tartrate)
- Metoprolol/HCTZ (generic for Lopressor HCT)
- Nadolol (generic for Corgard)
- Nadolol/Bendroflumethiazide (generic for Corzide)
- Nebivolol HCl (generic for Bystolic)
- **Pindolol (generic for Visken)**
- Propranolol HCl extended-release capsule (Inderal LA/Innopran XL)
- **Propranolol HCl solution (Hemangeol)**
- **Propranolol/HCTZ (generic for Inderide)**
- Sotylize (sotalol)**(manual review criteria)
- Tenoretic (atenolol/chlorthalidone)
- Tenormin (atenolol)
- **Timolol maleate (generic for Blocadren)**
- Toprol XL (metoprolol succinate ER)
- Ziac (bisoprolol/HCTZ)

3. NEUROPATHIC PAIN AGENTS

Preferred agents with criteria

- Duloxetine (generic for Cymbalta)
- Gabapentin capsules (generic for Neurontin)
- **Gabapentin tablets (generic for Neurontin)**
- **Pregabalin (generic for Lyrica)**

Nonpreferred agent with criteria

- Lidocaine patch (generic for Lidoderm)

Nonpreferred agents

- Cymbalta (duloxetine)
- **Drizalma sprinkle (duloxetine)**
- Gabapentin solution (generic for Neurontin)
- Gralise (gabapentin ER capsule)
- Horizant (gabapentin ER tablet)
- **Lidoderm patch (lidocaine)**
- Lyrica (pregabalin)
- Lyrica CR (pregabalin CR)
- Lyrica solution (pregabalin)
- Neurontin solution (gabapentin)
- Neurontin tablets and capsules (gabapentin)
- Pregabalin solution (generic for Lyrica)
- Pregabalin ER (generic for Lyrica CR)
- **Savella (milnacipran)**
- **Ztlido patch (lidocaine)**

Nonpreferred topical analgesia agent approval criteria:

- Submitted diagnosis post-herpetic neuralgia within the past 12 months; **OR**

- Paid claim in history identifying appropriate antiviral medication for post-herpetic neuralgia within the past 30 days
  - Acyclovir
  - Famciclovir
  - Valacyclovir

Preferred agent criteria:

- No therapeutic duplication with other neuropathic pain agents
- Allow one therapeutic duplication (90% overlap of last fill) with different date of service and same prescriber ID between pregabalin GCNs in previous 93 days
- Quantity edits apply
- This list is not all-inclusive of medications outlined in treatment guidelines for treating neuropathic pain. Arkansas Medicaid covers multiple medications without a PA for neuropathic pain not listed above.

4. SEDATIVE HYPNOTICS

BENZODIAZEPINES

Preferred agents with criteria

- Temazepam 15 mg and 30 mg (generic for Restoril)
- Triazolam (generic for Halcion)

Nonpreferred agents

- Estazolam (Prosom)
- Flurazepam (generic for Dalmane)
- Halcion (triazolam)
- Restoril (temazepam)
- Temazepam 7.5 mg and 22.5 mg (generic for Restoril)

NONBENZODIAZEPINES

Preferred agents with criteria

- **Eszopiclone (generic for Lunesta)**
- Zaleplon (generic for Sonata)
- Zolpidem (generic for Ambien)

Nonpreferred agents

- Ambien (zolpidem)
- Ambien CR (zolpidem ER)
- Belsomra (suvorexant)
- Dayvigo (Lemborexant)
- Doxepin (generic for Silenor)
- Edluar (zolpidem SL)
- Lunesta (eszopiclone)
- Ramelteon (generic for Rozerem)
- Rozerem (ramelteon)
- Silenor (doxepin)
- Zolpidem ER (generic for Ambien CR)
- Zolpidem SL tablet (generic for Edluar)

Nonpreferred agents with criteria

- Hetlioz capsule and suspension (tasimelteon)

Preferred agent criteria:

- No therapeutic duplication with other sedative hypnotics
- Quantity edits apply

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

EFFECTIVE IMMEDIATELY

1) HIDRADENITIS SUPPURATIVA

APPROVAL CRITERIA:

- Some medications/treatments recommended in Hidradenitis Suppurativa (HS) guidelines may not be a covered product/procedure by Arkansas Medicaid. Refer to the respective provider manual for additional information.
- Recipient with diagnosis of **Hurley Stage I HS** should use options from the following list (biologics are not recommended for Hurley Stage I):
    1) Topical clindamycin
    2) Oral tetracyclines (tetracycline, doxycycline, minocycline)
    3) Antiandrogenic agents (combined oral contraceptives, spironolactone, finasteride)
    4) Metformin
    5) Alternatives for refractory patients—clindamycin with rifampin, acitretin, dapsone
    6) Laser therapy
    7) Intralesional corticosteroids
    8) Topical resorcinol
    9) Surgical drainage
- Recipient with diagnosis of **Hurley Stage II:**
    - Recipient should follow treatment guidelines (e.g., *Journal of the American Academy of Dermatology*) https://www.jaad.org/action/showPdf?pii=S0190-9622%2819%2930368-8
    - Prior to beginning biologics, the recipient should have tried at least 2 of the following:
        - Oral tetracyclines for a minimum of 3 months (unless contraindicated)
        - Combination of rifampin and clindamycin for a minimum of 3 months (unless contraindicated)
        - Oral contraceptives for a minimum of 3 months (females only)
        - Oral retinoids for a minimum of 3 months (unless contraindicated)
        - Refractory after treatment—antibiotic therapy with adjunctive treatment of an antiandrogen, metformin, or oral contraceptives (when choosing adjunctive options, consideration the recipient's comorbidities)
    - Recipients who are refractory after at least two 3-month therapies or have progressed to Stage III during treatment may benefit from biologics
        - Adalimumab; **OR**
        - Infliximab (2nd line after adalimumab)
- Recipient with diagnosis of **Hurley Stage III** may begin a biologic without a trial from the list above
- Prescriber must submit chart notes with documentation of previous therapies tried including surgery or laser treatment
- Comorbidities that can increase HS severity must be addressed (list not all inclusive)
    - Tobacco use
    - Obesity
    - PCOS

EFFECTIVE IMMEDIATELY

2) SYNAGIS® (palivizumab) injection

Respiratory Syncytial Virus (RSV) causes acute respiratory illness in all ages, but the clinical manifestations vary based on age and health status. RSV is the most common cause of lower respiratory tract infection (LRTI) in children <1 year of age. Most pediatric RSV deaths occur in children born prematurely and those with underlying cardiopulmonary disease or other chronic conditions (e.g., immune deficiency).

Typically, seasonal outbreaks in our area occur from November to March with the peak in January or February. Arkansas Medicaid will continue to cover Synagis® during that timeframe for the reduction of serious lower respiratory tract infections caused by RSV in children at increased risk of severe disease as outlined by the American Academy of Pediatrics.

- https://pediatrics.aappublications.org/content/134/2/415
- https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_PA_Request_Form_Synagis.pdf

For instances when RSV prevalence is higher than normal during the "off-season", Arkansas Medicaid will consider Synagis® approval when:

- The child would meet the normal approval criteria as referenced in the 2014 AAP guidance at the time of request; AND
- One of the following:
  - RSV antigen test positivity rate is >10% for at least 2 consecutive weeks; OR
  - RSV PCR test positivity rate is >4% for at least 2 consecutive weeks.
- The maximum number of doses will remain at 5 for the typical RSV season. If an "off-season" outbreak occurs, additional doses may be allowed.

EFFECTIVE APPROXIMATELY 3/1/2022

3) Intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG)

POINT-OF-SALE APPROVAL CRITERIA:

- All IVIG and SCIG products will be subject to point-of-sale edits
- For a claim to process at POS, the recipient must have a billed diagnosis for an indication found in Table A in the last 2 years
- Recipients without a billed diagnosis from Table A will require a prior authorization request to be submitted by the prescriber. Each PA request will be reviewed on a case-by-case basis. The prescriber must submit the following:
  - Current chart notes
  - Diagnosis requiring immune globulin
- Criteria does not pertain to medically billed claims; only pertains to pharmacy claims

Table A—taken from DailyMed and MicroMedex 9/20/2021

FDA approved and non-FDA supported immune globulin indications
FDA approved indications
Primary Humoral Immunodeficiency
•Common variable immunodeficiency •X-linked agammaglobinemia •Congenital agammaglobinemia •Wiskott-Aldrich syndrome •Severe combined immunodeficiency
Chronic Immune Thrombocytopenic Purpura
Chronic Inflammatory Demyelinating Polyneuropathy
Kawasaki Syndrome
Multifocal Motor Neuropathy
B-cell Chronic Lymphocytic Leukemia
Dermatomyositis
Supported non-FDA approved indications
Acquired epidermolysis bullosa
Autoimmune hemolytic anemia
Autoimmune neutropenia
Bone marrow transplant
Bullous pemphigoid
Cytomegalovirus Infection (Treatment and prophylaxis)
Disseminated encephalomyelitis
Guillain-Barre Syndrome
Herpes gestationis
Kidney disease (Severe IgA nephropathy)
Linear IgA dermatosis
Lumbosacral radiculoplexus neuropathy
Lymphoproliferative disorder following transplantation
Myasthenia gravis
Ocular cicatricial pemphigoid
Pemphigus vulgaris
Polyarteritis nodosa
Pyoderma gangrenosum
Renal Transplant
Respiratory Syncytial Virus Infection
Stiff-person syndrome
Toxic shock syndrome
Uveitis
von Willebrand disorder

EFFECTIVE IMMEDIATELY

4) BREXAFEMME® (ibrexafungerp) 150 mg tablet

INDICATION:
BREXAFEMME is indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

DOSAGE:
The recommended dosage of BREXAFEMME in adult, post-menarchal pediatric females is 300 mg (two 150 mg tablets) administered approximately 12 hours apart (e.g., in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets). BREXAFEMME may be taken with or without food.

DOSE MODIFICATION:
With concomitant use of a strong CYP3A inhibitor (e.g., ketoconazole), administer BREXAFEMME 150 mg approximately 12 hours apart for one day.

APPROVAL CRITERIA:

- Recipient must be post-menarchal; **AND**
- Recipient must have a diagnosis of vulvovaginal candidiasis (VVC) **OR** a diagnosis consistent with FDA approved indication; **AND**
- Recipient must have failed (non-clearance of initial infection) after vaginal antifungal treatment AND fluconazole unless cannot tolerate azole antifungals; **AND**
- Prescriber must submit current chart notes

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber requests total dose greater than 600 mg; **OR**
- Prescriber has not tried an azole antifungal if no contraindication; **OR**
- Recipient is pregnant

QUANTITY EDITS:
#4 tablets / 30 days

EFFECTIVE IMMEDIATELY

5) REZUROCK™ (belumosudil) 200 mg tablet

INDICATION:
REZUROCK is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

DOSAGE:
The recommended dose of REZUROCK is 200 mg given orally once daily until progression of chronic GVHD that requires new systemic therapy.

DOSE MODIFICATION:

Table 1: Recommended Dosage Modifications for REZUROCK for Adverse Reactions

Adverse Reaction	Severity*	REZUROCK Dosage Modifications
Hepatotoxicity **[see Adverse Reactions (6.1)]**	Grade 3 AST or ALT (5x to 20x ULN) or Grade 2 bilirubin (1.5x to 3x ULN)	Hold REZUROCK until recovery of bilirubin, AST and ALT to Grade 0-1, then resume REZUROCK at the recommended dose.
	Grade 4 AST or ALT (more than 20x ULN) or Grade ≥ 3 bilirubin (more than 3x ULN)	Discontinue REZUROCK permanently.

Strong CYP3A inducers—increase dose of REZUROCK to 200 mg twice daily
Proton pump inhibitors—increase dose of REZUROCK to 200 mg twice daily

APPROVAL CRITERIA:

- Recipient must be ≥ 12 years of age; **AND**
- Recipient must be diagnosed with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient of reproductive potential should use effective contraception; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous therapies tried with response; **AND**
    - Current labs including CBC with differential, LFTs, and CMP; **AND**
    - Negative pregnancy test for female recipient of reproductive potential

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient demonstrates disease progression; **OR**
- Recipient develops hepatotoxicity while on the medication with either Grade 4 AST or ALT (20X ULN) or Grade 3-4 bilirubin (3X ULN)
- Recipient has the following labs values at baseline (provide if available):
    - Platelets < 50 X 10^9/L
    - ANC < 1.5 X 10^9/L
    - AST or ALT > 3X ULN
    - Total bilirubin > 1.5X ULN
    - eGFR < 30 mL/min/1.73m^2
    - FEV1 ≤ 39% (patients with pulmonary manifestations)

CONTINUATION CRITERIA:

- Recipient demonstrates an improvement in baseline symptoms associated with GVHD; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Response to treatment; **AND**
    - Current labs including CBC with differential, LFTs, and CMP

QUANTITY EDITS:

#30/ 30 days

EFFECTIVE IMMEDIATELY

6) BYLVAY™ (odevixibat) 200 mcg and 600 mcg pellets & 400 mcg & 1200 mcg capsules

INDICATION:
BYLVAY is indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

Limitations of Use
BYLVAY may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

DOSAGE:
- The recommended dosage of BYLVAY is 40 mcg/kg once daily in the morning with a meal.
- If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.
- BYLVAY capsules are intended for use by patients weighing 19.5 kilograms or above.
- BYLVAY oral pellets are intended for use by patients weighing less than 19.5 kilograms

Table 1. Recommended Dosage for 40 mcg/kg/day

Body Weight (kg)	Total Daily Dose (mcg)
7.4 and below	200
7.5 to 12.4	400
12.5 to 17.4	600
17.5 to 25.4	800
25.5 to 35.4	1200
35.5 to 45.4	1600
45.5 to 55.4	2000
55.5 and above	2400

Table 1 below shows the recommended weight-based total daily dosage needed for the recommended dosage at 40 mcg/kg once daily.

DOSE MODIFICATION:
- Interrupt if new onset liver test abnormalities occur and restart at the lowest dose of 40 mcg/kg once return to baseline
- Discontinue if develops a hepatic decompensation event

APPROVAL CRITERIA:
- Recipient must be ≥ 3 months of age; **AND**
- Recipient must have a confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC) with a baseline presence of pruritus **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient has elevated serum bile acid concentration; **AND**
- Recipient has documented failure of ursodeoxycholic acid (Ursodiol) AND cholestyramine unless there is a documented contraindication; **AND**

- Recipient should continue ursodeoxycholic acid concomitantly**; AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including serum bile acids, serum levels of vitamins A, D, E, and INR (for vitamin K) and LFTs; **AND**
  - Genetic testing results with PFIC type and presence or absence of the ABCB11 variant
- Initial approval for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3); **OR**
- Recipient has decompensated liver disease; **OR**
- Recipient should discontinue BYLVAY if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 120 mcg/kg per day; **OR**
- Recipient is not concurrently ordered ursodeoxycholic acid.

CONTINUATION CRITERIA:

- Recipient must have a documented decrease in pruritis and/or a decrease in serum bile acid after dose titration; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including bile acids, serum levels of vitamins A, D, E, and INR (for vitamin K) and LFTs; **AND**
  - Dose required

QUANTITY EDITS:

200 mcg pellets--#62 per 31 days
600 mcg pellets--#31 per 31 days
400 mcg capsules--#155 per 31 days
1200 mcg capsules--#155 per 31 days

EFFECTIVE IMMEDIATELY

7) AEMCOLO™ (rifamycin) 194 mg tablet

INDICATION:
AEMCOLO is indicated for the treatment of travelers' diarrhea (TD) caused by non-invasive strains of Escherichia coli in adults.

Limitations of Use
AEMCOLO is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of Escherichia coli

DOSAGE:
The recommended dose of AEMCOLO is 388 mg (two tablets) orally twice daily (in the morning and evening) for three days.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be diagnosed with travelers' diarrhea caused by non-invasive strains of Escherichia coli **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous treatment; **AND**
    - Medical necessity over other antibiotics available without a PA

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber ordered a dosage or therapy duration outside of FDA indication or support on the official Compendia; **OR**
- Recipient has a fever and/or bloody stools

CONTINUATION CRITERIA:

- Recipient continues to have symptoms of travelers' diarrhea; **AND**
- Prescriber must submit the following:
    - Current fecal culture & sensitivity report documenting an E. coli infection

QUANTITY EDITS:
#12/ 23 days

EFFECTIVE IMMEDIATELY

8) WELIREG™ (belzutifan) 40 mg tablet

INDICATION:
WELIREG is indicated for treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.

DOSAGE:
The recommended dosage of WELIREG is 120 mg administered orally once daily until disease progression or unacceptable toxicity. WELIREG should be taken at the same time each day and may be taken with or without food.

DOSE MODIFICATION:
The recommended dose reductions are:

- First dose reduction: WELIREG 80 mg orally once daily
- Second dose reduction: WELIREG 40 mg orally once daily
- Third dose reduction: Permanently discontinue

Recommended Dosage Modifications for Adverse Reactions:

1. Anemia—Hemoglobin < 9 g/dL withhold until Hg ≥ 9 g/dL then resume at reduced dose; if life-threatening anemia, consider permanent discontinuation
2. Hypoxia—Decreased oxygen saturation with exercise, withhold until resolved then resume at same dose or at reduced dose depending on severity; Decreased oxygen saturation with rest, withhold until resolved then resume at reduced dose or discontinue depending on severity

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be diagnosed with von Hippel-Lindau (VHL) disease and require therapy for renal cell carcinoma, central nervous system hemangioblastoma, or pancreatic neuroendocrine tumor but does not require immediate surgery **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient of reproductive potential should use effective non-hormonal contraception; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Previous therapies tried; **AND**
    - Documentation of diagnosis (i.e., MRI results, fundoscopy report, abdominal US/MRI results, or blood & urinary catecholamine metabolites) with tumor size; **AND**
    - Current labs; **AND**
    - Baseline oxygen saturation; **AND**
    - Pregnancy test results of female recipient of reproductive potential
- Initial PA approved for 1 month

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient with a hemoglobin <9 g/dL should have medication withheld (If possible, resume at reduced dose if Hb increases to ≥9 g/dL.) and permanently discontinue depending on the severity of anemia; **OR**
- Recipient with decreased oxygen saturation (pulse oximeter <88%) should have medication withheld (If possible, resume at same or reduced dose depending on severity.) and permanently discontinue for life-threatening or recurrent symptomatic hypoxia; **OR**
- Recipient has severe renal or hepatic impairment; **OR**
- Recipient requires immediate need for tumor surgery

CONTINUATION CRITERIA:

- Recipient does not have intolerable side effects; **AND**
- Recipient has a positive response on tumor size no later than a year after initiating therapy; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs; **AND**
    - Oxygen saturation if recipient has hypoxia symptoms; **AND**
- Subsequent PAs approved for 3 months

QUANTITY EDITS:

#90/ 30 days

EFFECTIVE APRIL 1, 2022

9) ANTIEPILEPTIC MEDICATIONS QUANTITY EDITS

Anticonvulsants are a diverse group of pharmacological agents used in the treatment of epileptic seizures. Anticonvulsants are also increasingly being used in the treatment of bipolar disorder and borderline personality disorder, as mood stabilizers, and for the treatment of neuropathic pain.

After the utilization report review, it was determined that many drugs in this class are dosed outside of the FDA approved dosing recommendations. Quantity edits will be implemented for all products in this class except for those few drugs that are dosed by weight and have no maximum dose documented in the package insert.

For the products that have significant pharmacy claims well outside of the FDA approved dosing recommendations, the maximum quantity allowed will be for a slightly higher dose than FDA approved doses to minimize the need for excessive PA submissions.

After the quantity edits are put into place, any patients with doses outside of the quantity limits will require a prior authorization. The prescriber should submit the following regardless of diagnosis:

1. Chart notes
2. Chronology documentation for the current dose
3. Documentation of tolerance to the medication with dose titration
4. Documentation of improved response with these outlying doses
5. Blood levels of the product

QUANTITY LIMITS will be provided at a later date.

EFFECTIVE JANUARY 1, 2022

10) DOSE OPTIMIZATION ON VARIOUS DRUG CLASSES

Dose Optimization refers to the identification of patients who receive multiple units (tablets or capsules) of a lower strength and taking action to consolidate (or 'optimize') the dosing regimen to an equivalent daily dosage of the same medication given as a single unit. This intervention is particularly successful for those medications available in a number of different strengths with parity (or near parity) pricing. This can reduce pill burden, simplify therapeutic regimens, improve treatment compliance, and reduce pharmacy spend.

Beginning January 1, 2022, medications in the following classes will not take up a Medicaid slot for our clients: Blood pressure, diabetes, blood modifiers, asthma/COPD inhalers, and cholesterol agents. Many medications in these 5 drug classes are relatively inexpensive generics, and some products already have quantity limits in place. Therefore, it may seem reviewing for dose optimization is not necessary. But for consistency, all products will be updated with maximum quantities.

QUANTITY LIMITS:


Diabetes medications maximum quantity.pd


Blood modifiers medications maximun


Blood pressure medication maximum


Cholesterol medication maximum

11) FRIENDLY REMINDERS

1. Any questions concerning various Medicaid topics (e.g., Medicaid enrollment, prescription coverage, provider manuals, and billing policies) may be researched using one of the following links.

- **https://medicaid.mmis.arkansas.gov/**
- **https://humanservices.arkansas.gov/**
- **https://arkansas.magellanrx.com/**

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."

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

3. **For vaccine billing and updates, visit the Welcome to Arkansas webpage.**
https://humanservices.arkansas.gov/
https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/
For adult vaccines (ages 18 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:
G0008 – Influenza immunization
90471 – First vaccine administered
90472 – Subsequent vaccines administered
The **Injection administration code, T1502** will continue to be payable for clients of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only.
If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211.
Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website:
https://medicaid.mmis.arkansas.gov/Provider/Docs/Docs.aspx/
If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy:
https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/

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 clients 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 clients, including clients 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."

6. **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.**

7. **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 clients and once per 60 days per drug class for LTC clients.

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/.

8. **HARD EDIT ON EARLY REFILL:**

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 client for the higher dose or an early refill PA will not be approved.

Controlled drugs:
The hard edit disallowing early refills (ER) for controlled drugs sooner than 90% of days' supply expended was implemented January 20, 2021. This change includes opioids, CII stimulants, benzodiazepines, sedative hypnotics, etc.

9. **REFILL TOO SOON ACCUMULATION LOGIC:** When a pharmacy refills a prescription claim early, 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.

Non-controlled drugs:
Once the client has accumulated an *extra* 12 days' supply for that GSN for non-controlled drugs, any incoming claim that is early will reject at point of sale. The accumulation edit is set so that the client cannot accumulate more than an *extra* 12 days' supply early during a 180-day period for non-controlled drugs.

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Controlled drugs:
The RTS logic with Early Refill Accumulation Limit edit for controlled drugs will only allow an *extra* 7-days' supply accumulation through early fills in previous 180-day period.

10. **REVERSE AND CREDIT MEDICAID PRESCRIPTIONS NOT PROVIDED TO CLIENT:** Pharmacies are required to reverse and credit back to Medicaid original prescriptions and refills if the medication was not provided to the client. Pharmacies should reverse and credit Medicaid within 14 days of the date of service for any prescription that was not provided to the client. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.

11. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:**

< 18 YEARS OF AGE:
Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Clients 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.

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 may be found at the following link. https://arkansas.magellanrx.com/client/docs/rxinfo/MedInformedConsent.pdf

< 10 YEARS OF AGE:
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 psychiatrist.

12. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID CLIENTS WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that client can be billed using the client'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.

13. **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

14. **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.

15. **OPIOID INFORMATION ON THE MAGELLAN WEBSITE:** To provide educational materials to prescribers and pharmacists on opioid dosing, opioid use disorder, medication assisted treatment and polypharmacy, an opioid information tab has been added to the Magellan Health website.
https://arkansas.magellanrx.com/client/documents

16. **HEPATITIS C TREATMENT INFORMATION**
Educational information on treating Hepatitis C along with treatment consultations may be obtained through the Clinician Consultation Center.
1) Link for the Clinician Consultation Center—
http://www.hepcap.org/hepatitis-c-consultation-warmline/
2) Hepatitis C Warmline for phone consultation—(844) HEP-INFO or (844) 437-4636

The clinical consultation staff may give advice on any of the following topics:
- HCV staging & monitoring
- Regimen selection & dosing
- Drug interactions
- HIV/HCV management strategies
- Prior HCV treatment failure, including management of complex clinical problems such as cirrhosis and renal disease
- HCV transmission & prevention
- HCV screening & diagnostic testing
- HCV in special populations (pregnancy, co-occurring substance use and/or alcohol use disorders, psychiatric disorders, post-transplant, ESRD/dialysis, pediatrics)

The Clinician Consultation Center is not affiliated with Arkansas Medicaid, but the information may be useful for providers in our state and provided only as an educational tool.

17. **PLACE OF SERVICE**
General Information
Arkansas Medicaid is updating the National Place of Service Code in the Pharmacy manual and in the billing rules to comply with the national standards, and to ensure pharmacies are billing consistently. Effective 8/1/2021, the current code of "99" will be replaced with the correct Place of Service Code for Pharmacy "01".

If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 toll-free or locally at (501) 376-2211. If you need this material in an alternative format, such as large print, please contact the Office of Rules Promulgation at (501) 396-6428.

Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rule making, and remittance advice (RA) messages are available for download from the Division of Medical Services website.

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.