



**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 *Cynthia Neuhofer*

DATE: November 27, 2019

SUBJ: **AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board October 16, 2019 meeting for the following: Manual review criteria for** CABLIVI® (caplacizumab-yhdp) intravenous or subcutaneous injection, PIQRAY® (alpelisib) 50mg, 150mg and 200mg tablet, XPOVIO™ (selinexor) 20mg tablets, IRESSA® (gefitinib) 250mg tablet, NUBEQA™ (darolutamide) 300mg tablet, TURALIO™ (pexidartinib) 200mg capsule, INREBIC® (fedratinib hydrochloride) 100mg capsule, NUCALA® (mepolizumab) 100mg/mL SYRINGE/AUTOINJECTOR, BAQSIMI™ 3mg (glucagon) powder, AND ROZLYTREK™ (entrectinib) 100mg and 200mg capsules. **Update on current criteria for** Truvada® (emtricitabine and tenofovir disoproxil fumarate) 100-150mg, 133-200mg, 167-250mg and 200-300mg tablets, INGREZZA® (valbenazine) 40mg and 80mg capsules, AUSTEDO® (deutetrabenazine) 6mg, 9mg and 12 mg tablets, AND HEMLIBRA® (emicizumab) 30mg/mL, 60mg/0.4mL, 105mg/0.7mL and 150mg/mL Subcutaneous injections

Preferred Drug List (PDL) therapeutic classes from the November 13, 2019 Drug Review Committee Meeting for the following: Antimigraine Agents (Triptans only), COPD agents, Inhaled Glucocorticoids, Multiple Sclerosis Agents, NSAIDs (oral and topical), Opiate Dependence Treatments (Injection only) and Pulmonary Arterial Hypertension (oral, inhaled and injection).

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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) **[Opium Tincture and Hyoscyamine](#)**

The Magellan Help Desk has received multiple requests for the coverage of opium tincture and hyoscyamine. These products are *excluded* medications in the Arkansas Medicaid Pharmacy Program. These drugs have not been found by the FDA to be safe and effective and have not been approved by the FDA.

4) **[Preferred inhaled antibiotics](#)**

The inhaled antibiotics class was reviewed by the Drug Review Committee on August 14, 2019. The preferred and non-preferred list has been updated. The provider memo posted on August 8, 2019 was incorrect. The correct preferred drug list is as follows:

PREFERRED

Kitabis®
Bethkis™

NONPREFERRED

Tobramycin (AG and generic only)
TOBI®
TOBI Podhaler®
Cayston®
Arikayce® (requires manual review)

5) **[Ranexa 500mg and 1000mg tablets](#)**

Ranexa is indicated for the treatment of chronic angina. Currently, Ranexa is considered a State Supported Brand medication. Multiple manufacturers have brought generic Ranexa to the market, bringing the cost down, and it is no longer beneficial for the State to support the brand name. Effective December 1, 2019, pharmacies should begin processing claims with the generic (ranolazine) for proper payment. At that point, brand name Ranexa will require a Brand Medically Necessary prior authorization.

6) **[Preferred Oral Agents for Opioid Use Disorder](#)**

Beginning January 1, 2020, as required by Act 964 of 2019, the following changes will be made to the preferred buprenorphine products on the Arkansas Medicaid evidence-based preferred drug list:

- The preferred medications will not require a PA if there is a valid prescription for opioid use disorder and compliance with the medication-assisted treatment guidelines,
- Prescriptions for medications will not take up a Medicaid slot.
- Prescriptions for medications will not require a copay by the beneficiary.

Maximum quantity edits apply per FDA dosing recommendations and therapeutic duplication limitations will continue to apply. If buprenorphine products have been dispensed in the last 90 days, the opioid prescription will deny and require a prior authorization.

Non-preferred medications will continue to require a PA. Currently, the preferred medications are Suboxone® films and Buprenorphine SL tablets. Review the pharmacy vendor website for any changes to the preferred medication list.

7) Coverage of Tobacco Cessation Products

Pursuant to Act 959 and effective for claims with dates of service on or after January 1, 2020, coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol are available without prior authorization (PA) to eligible Medicaid beneficiaries.

Coverage and Limitations

- Reimbursement for tobacco cessation products is available for all prescription and over the counter (OTC) products, and subject to be within FDA prescribing and dosing limitations.
- Additional prescription benefits are allowed per month for tobacco cessation products and will not count against the monthly prescription benefit limit.
- Tobacco cessation products are not subject to co-pay.
- OTC as well as any prescription products are eligible for reimbursement. OTC products are not covered for long-term care residents.

EFFECTIVE January 1, 2020:

PREFERRED DRUGS LIST (PDL):

Antimigraine Agents (Triptans only)

Preferred Agents

- Sumatriptan succinate tablet (Imitrex)
- Imitrex nasal spray (Sumatriptan) (BRAND ONLY)
- Rizatriptan benzoate tablet (Maxalt)
- Rizatriptan benzoate disintegrating (Maxalt MLT)
- Zomig nasal spray (Zolmitriptan) (BRAND ONLY)

Preferred Agents WITH Criteria

- Sumatriptan 6mg/0.5ml vial (Imitrex)
- Sumatriptan 4mg/0.5ml kit refill (Imitrex)
- Sumatriptan 6mg/0.5ml kit refill (Imitrex)

Nonpreferred Agents

- Almotriptan malate tablet (Axert)

- Eletriptan HBr (Relpax)
- Frovatriptan succinate tablet (Frova)
- Naratriptan HCl tablet (Amerge)
- Sumatriptan succinate/naproxen sodium tablet (Treximet)
- Sumatriptan nasal powder (Onzetra Xsail)
- Sumatriptan nasal spray (Tosymra)
- Sumatriptan nasal spray (Imitrex) (GENERIC ONLY)
- Sumatriptan syringe
- Sumatriptan Autoinjector (Zembrace Symtouch)
- Zolmatriptan tablet (Zomig)
- Zolmatriptan disintegrating (Zomig ZMT)

COPD Agents

Preferred Agents WITH Criteria

- Glycopyrrolate/formoterol fumarate inhaler (Bevespi Aerosphere™)
- Ipratropium bromide inhaler (Atrovent® HFA)
- Ipratropium bromide nebulizer solution
- Ipratropium bromide/albuterol sulfate inhaler (Combivent® Respimat®)
- Tiotropium bromide inhaler (Spiriva® Handihaler®)

Nonpreferred Agents

- Aclidinium bromide inhaler (Tudorza® Pressair®)
- Glycopyrrolate capsule (Seebri™ Neohaler®)
- Glycopyrrolate solution (Lonhala® Magnair®)
- Indacaterol maleate/glycopyrrolate capsule (Utibron® Neohaler®)
- Ipratropium bromide/albuterol sulfate nebulizer solution
- Revfenacin solution (Yupelri®)
- Roflumilast tablet (Daliresp®)
- Tiotropium bromide inhaler (Spiriva® Respimat®)
- Tiotropium bromide/olodaterol HCl inhaler (Stiolto® Respimat®)
- Umeclidinium bromide inhaler (Incruse® Ellipta®)
- Umeclidinium bromide/vilanterol trifenate inhaler (Anoro® Ellipta®)

Inhaled Glucocorticoids

Preferred Agents WITH Criteria (ICS only agents)

- Budesonide 0.25mg, 0.5mg and 1mg respules (Pulmicort Respules®) (GENERIC ONLY)
- Fluticasone propionate inhaler (Flovent HFA®)
- Mometasone furoate inhalation powder (Asmanex® Twisthaler®)

Nonpreferred

- Beclomethasone HFA inhalation aerosol (QVAR® Redihaler®)
- Budesonide inhaler (Pulmicort Flexhaler®)
- Ciclesonide inhalation aerosol (Alvesco®)
- Fluticasone furoate inhalation powder (Arnuity® Ellipta®)
- Fluticasone propionate disk (Flovent® Diskus)
- Fluticasone propionate (Armonair™ RespiClick®)

- Mometasone furoate inhalation aerosol (Asmanex® HFA)

Preferred WITH Criteria (ICS/LABA combination)

- Budesonide/formoterol fumarate dihydrate inhalation aerosol (Symbicort®)
- Fluticasone propionate/salmeterol inhalation powder (Advair® Diskus®) (BRAND ONLY)
- Mometasone furoate/formoterol fumarate dihydrate inhalation aerosol (Dulera®)

Nonpreferred

- Fluticasone furoate/vilanterol inhalation powder (Breo® Ellipta®)
- Fluticasone propionate/salmeterol inhalation (Advair® HFA)
- Fluticasone propionate/salmeterol inhalation powder (GENERIC ONLY)
- Fluticasone propionate/salmeterol powder (AirDuo™ RespiClick®)
- Fluticasone propionate/salmeterol powder (Wixela™ Inhub™)
- Fluticasone furoate/umeclidinium bromide/vilanterol trifenate powder (Trelegy® Ellipta®)

Multiple Sclerosis

Preferred Agents NO Criteria

- Glatiramer acetate 20mg injection (Copaxone®) (BRAND ONLY)
- Interferon Beta – 1A injection pen and syringe (Avonex®)

Preferred Agents WITH Criteria

- Dimethyl fumarate capsule (Tecfidera® and Tecfidera® Starter Pak) (Manually reviewed)

Nonpreferred agents

- Cladribine (Mavenclad®)
- Dalfampridine (Ampyra®) (Manually reviewed)
- Fingolimod (Gilenya®)
- Glatiramer acetate 20mg injection (Generic Copaxone®)
- Glatiramer acetate 40mg injection (Brand and Generic Copaxone®)
- Glatiramer acetate 20mg injection (Glatopa®)
- Interferon Beta – 1A/albumin (Rebif®)
- Interferon Beta – 1B injection (Betaseron®)
- Interferon Beta – 1B vial and kit (Extavia®)
- Interferon Beta – 1A pegylated (Plegridy®)
- Siponimod (Mayzent®)
- Teriflunomide (Aubagio®)

Anti-inflammatory Agents (NSAIDs)

Preferred Agents

- Celecoxib capsule (Celebrex)
- Diclofenac sodium 25mg, 50mg and 75mg tablet (Voltaren)
- Diclofenac sodium gel topical (Voltaren Gel)
- Ibuprofen 100mg/5ml suspension; 400mg, 600mg 800mg tablet (Motrin)
- Indomethacin 25mg, 50mg capsules (Indocin)
- Meloxicam 7.5mg, 15mg tablet (Mobic)

- Nabumetone (Relafen)
- Naproxen 250mg, 375mg 500mg tablet (Naprosyn)
- Naproxen 375mg, 500mg enteric-coated tablet (EC-naprosyn)
- Naproxen sodium 275mg and 550mg tablet (Anaprox)

Preferred Agent WITH Criteria

- Ketorolac tablet (Toradol)

Nonpreferred Agents

- Diclofenac epolamine (Flector)
- Diclofenac potassium (Cambia, Cataflam, Zipsor)
- Diclofenac sodium ER 100mg tablet (Voltaren XR)
- Diclofenac sodium 1.5% and 2% topical (Pennsaid)
- Diclofenac sodium/misoprostol tablet (Arthrotec)
- Diclofenac submicronized (Zorvolex)
- Diflunisal tablet (Dolobid)
- Etodolac tablet (Lodine)
- Fenoprofen capsule (Nalfon)
- Flurbiprofen tablet (Ansaid)
- Ibuprofen/famotidine (Duexis)
- Indomethacin 75mg SA capsule; 50mg suppository; 25mg/ml suspension (Indocin); 25mg capsule (Tivorbex); 20mg and 40mg capsule (Tivorbex)
- Ketoprofen 50mg, 75mg capsule (Orudis)
- Ketoprofen 200mg extended-release capsules (Oruvail)
- Ketorolac nasal spray (Sprix)
- Meclofenamate sodium (Meclomen)
- Mefenamic acid (Ponstel)
- Meloxicam tablet, orally disintegrating tablet (QMIZ)
- Meloxicam submicronized (Vivlodex)
- Naproxen/esomeprazole magnesium (Vimovo)
- Naproxen suspension (Naprosyn)
- Naproxen sodium 375mg and 500mg extended-release tablet (Naprelan)
- Oxaprozin tablet (Daypro)
- Piroxicam capsules (Feldene)
- Sulindac tablet (Clinoril)
- Tolmetin sodium tablet (Tolectin)

Injectable Medication Assisted Treatment (MAT) Formulations

Preferred WITH Criteria

- Naltrexone (Vivitrol®)

Buprenorphine (Sublocade®) will not be a covered pharmacy benefit but may be available as a medical benefit.

Pulmonary Arterial Hypertension

Preferred Oral Agents WITH PA Criteria

- Ambrisentan tablet (Letairis®) (BRAND ONLY)

- Bosentan tablet (Tracleer®) (BRAND ONLY)
- Sildenafil tablet (Revatio®)
- Tadalafil tablet (Adcirca®)

Nonpreferred Oral Agents

- Ambrisentan tablet (GENERIC ONLY)
- Bosentan tablet (GENERIC ONLY)
- Bosentan 32mg tablet for suspension (Tracleer®)
- Macitentan tablet (Opsumit®)
- Riociguat tablet (Adempas®)
- Selexipag tablet (Uptravi®)
- Sildenafil suspension (Revatio®)
- Treprostinil tablet (Orenitram ER®)

Preferred Inhalation and Injectable Agents

- Epoprostenol vial (Veletri®, Flolan®) (GENERIC ONLY)
- Sildenafil vial (Revatio®)
- Treprostinil vial (Remodulin®) (GENERIC ONLY)

Nonpreferred Inhalation and Injectable Agents

- Iloprost inhalation solution (Ventavis®)
- Treprostinil inhalation solution (Tyvaso®)

PRIOR AUTHORIZATION DRUG CRITERIA, NEW OR REVISED, FOR THE FOLLOWING DRUGS:

EFFECTIVE February 19, 2020:

- 1) [Truvada® \(emtricitabine and tenofovir disoproxil fumarate\) 100-150mg, 133-200mg, 167-250mg and 200-300mg tablets](#)

INDICATION:

Truvada® is a two-drug combination of emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF), both HIV-1 nucleoside analog reverse transcriptase inhibitors, and is indicated:

- in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg.
- in combination with safer sex practices for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada® for HIV-1 PrEP.

If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting PrEP for at least one month and reconfirm HIV-1 status or use a test cleared by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection.

When considering Truvada® for HIV-1 PrEP, factors that help to identify individuals at risk may include:

- has partner(s) known to be HIV-1 infected, or

- engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as:
 - inconsistent or no condom use
 - diagnosis of sexually transmitted infections
 - exchange of sex for commodities (such as money, food, shelter, or drugs)
 - use of illicit drugs or alcohol dependence
 - incarceration
 - partner(s) of unknown HIV-1 status with any of the factors listed above

DOSING:

- Testing: Prior to or when initiating Truvada® test for hepatitis B virus infection. Prior to initiation and during use of Truvada®, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
- HIV-1 Screening: Screen all patients for HIV-1 infection before initiating Truvada® for HIV-1 PrEP and at least once every 3 months while taking Truvada®.

Treatment of HIV-1 Infection

- Recommended dosage in adults and pediatric patients weighing at least 35 kg: One Truvada® tablet (containing 200 mg of FTC and 300 mg of TDF) once daily taken orally with or without food.
- Recommended dosage in pediatric patients weighing at least 17 kg: One Truvada® low-strength tablet (100 mg/150 mg, 133 mg/200 mg, or 167 mg/250 mg based on body weight) once daily taken orally with or without food.
- Recommended dosage in renally impaired HIV-1 infected adult patients:
 - Creatinine clearance (CrCl) 30–49 mL/min: 1 tablet every 48 hours.
 - CrCl below 30 mL/min or hemodialysis: Truvada® is not recommended.

HIV-1 Pre-Exposure Prophylaxis (PrEP)

- Recommended dosage in HIV-1 uninfected adults and adolescents weighing at least 35 kg: One Truvada® tablet (containing 200 mg of FTC and 300 mg of TDF) once daily taken orally with or without food.
- Recommended dosage in renally impaired HIV-uninfected individuals: The safety and effectiveness of the dosing interval adjustment recommendations in patients with moderate renal impairment (creatinine clearance 30–49 mL/min) have not been clinically evaluated. Truvada® is not recommended in HIV-uninfected individuals if CrCl is below 60 mL/min.

Creatinine Clearance (mL/min)*			
	≥50	30–49	<30
Recommended Dosing Interval	Every 24 hours	Every 48 hours	Not recommended

APPROVAL CRITERIA:

***Remove manual review criteria for PrEP and remove Point-of-sale (POS) approval criteria to prevent barriers to HIV/AIDS treatment. Keep POS denial criteria concerning therapeutic duplication.

Therapeutic duplication edits for Truvada®, Descovy®, Emtriva® and Viread®:

- If there is a paid claim within previous 30 days for Descovy®, Emtriva® or Viread®, Truvada® will deny at POS.
- If there is a paid claim within previous 30 days for Descovy®, Emtriva® or Truvada®, Viread® will deny at POS.
- If there is a paid claim within previous 30 days for Descovy®, Truvada® or Viread®, Emtriva® will deny at POS.
- If there is a paid claim within previous 30 days for Truvada®, Viread® or Emtriva®, Descovy®, will deny at POS.

***Keep quantity edits for Truvada®, Descovy®, Emtriva® and Viread® of 1 dose per day.
***Any generics that become available will have the same criteria.

EFFECTIVE IMMEDIATELY:

2) Ingrezza® (valbenazine) 40mg and 80mg capsules

INDICATION:

Ingrezza® is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.

DOSING:

The initial dose for Ingrezza® is 40 mg once daily. After one week, increase the dose to the recommended dose of 80 mg once daily. Continuation of 40 mg once daily may be considered for some patients.

DOSING MODIFICATIONS:

- 1) The recommended dose for patients with moderate or severe hepatic impairment (Child-Pugh score 7 to 15) is Ingrezza® 40 mg once daily
- 2) Consider reducing Ingrezza® dose based on tolerability for known CYP2D6 poor metabolizers.
- 3) Concomitant use of strong CYP3A4 inducers with Ingrezza® is not recommended (Ex: rifampin, carbamazepine and phenytoin).
- 4) Reduce Ingrezza® dose to 40 mg once daily when Ingrezza® is co-administered with a strong CYP3A4 inhibitor (Ex: itraconazole, ketoconazole and clarithromycin).
- 5) Consider reducing Ingrezza® dose based on tolerability when Ingrezza® is co-administered with a strong CYP2D6 inhibitor (Ex: paroxetine, fluoxetine and quinidine).

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Beneficiary must be 18 years of age or older; **AND**
- Prescriber must submit chart notes with documentation on the impact of TD symptoms with activities of daily living; **AND**
- Beneficiary must have a diagnosis of moderate to severe tardive dyskinesia meeting the following DSM-5 criteria:
 - Involuntary athetoid or choreiform movements; **AND**
 - History of treatment with dopamine receptor blocking agent (DRBA) (e.g. antipsychotics or metoclopramide); **AND**
 - Symptom duration lasting longer than 4 to 8 weeks; **AND**
- Ingrezza® must be prescribed by a neurologist or psychiatrist; or prescriber has consulted with a neurologist or psychiatrist if symptoms are due to antipsychotic usage. Ingrezza® may also be prescribed by gastroenterology if symptoms are due to metoclopramide usage; **AND**
- Beneficiary must not be suicidal or have violent behavior; **AND**

- Prescriber must submit the completed Medicaid “Ingrezza® / Austedo® Statement of Medical Necessity” form with the initial request as part of the manual review; **AND**
Updated form



ARRx_SMN_Form_In
grezza_Austedo2.pdf

- Prescriber must submit a baseline Abnormal Involuntary Movement Scale (AIMS) form as part of the manual review; **AND**
- Female beneficiary must not be pregnant or breastfeeding; **AND**
- Beneficiary must not be taking monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor or concomitant strong CYP3A4 inducers (e.g. rifampin, carbamazepine, and phenytoin); **AND**
- Beneficiary must not exceed Ingrezza® 40mg daily if also taking strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, and clarithromycin); **AND**
- Beneficiary must not exceed Ingrezza® 40mg daily if has moderate or severe hepatic impairment (Child-Pugh score 7 to 15); **AND**
- Beneficiary must not have congenital long QT Syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval and prescriber must provide attestation; **AND**
- If beneficiary has taken bengtropine, or any other agent for EPS symptoms, provider must submit data documenting the response to the agent; **AND**
- Beneficiary must not have severe renal impairment (creatinine clearance <30 mL/min) and prescriber must provide attestation; **AND**
- Initial PAs not to exceed 3 months; once compliant on a maintenance dose, PAs may be approved for a maximum of 6 months.

DENIAL CRITERIA:

- Beneficiary is < 18 years of age; **OR**
- Beneficiary is not compliant on prescribed dose after previous approval; **OR**
- Prescriber requests a dose > 80mg/ day; **OR**
- Prescriber requests a dose > 40mg/ day for beneficiaries with moderate or severe hepatic impairment or beneficiary takes strong CYP3A4 inhibitors; **OR**
- Beneficiary does not have an improvement from baseline AIMS score or a positive clinical response to therapy; **OR**
- Beneficiary does not meet the approval criteria

CONTINUATION CRITERIA:

- Beneficiary must be compliant on prescribed dose; **AND**
- Prescriber must submit current chart notes; **AND**
- Prescriber must provide an updated AIMS form and documentation of clinical response to therapy every 6 months; **AND**
- Beneficiary must show an improvement from baseline AIMS score and/or have a positive clinical response to therapy; **AND**
- Beneficiary must continue to meet approval criteria

QUANTITY EDITS:

40mg capsules = #30 per 30 days (The initial PA will be approved for #60 capsules for titration for 1 month only.)

80mg capsules = #30 per 30 days

EFFECTIVE IMMEDIATELY:

3) Austedo® (deutetrabenazine) 6mg, 9mg and 12mg tablets

INDICATION:

AUSTEDO® is indicated for the treatment of:

- chorea associated with Huntington's disease
- tardive dyskinesia in adults

DOSING:

The dose of Austedo® is determined individually for each patient based on reduction of chorea or tardive dyskinesia and tolerability. When first prescribed to patients who are not being switched from tetrabenazine (a related VMAT2 inhibitor), the recommended starting dose of Austedo® is 6 mg administered orally once daily for patients with Huntington's disease and 12 mg per day (6 mg twice daily) for patients with tardive dyskinesia.

- The dose of Austedo® may be increased at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg.
- Administer total daily dosages of 12 mg or above in two divided doses.
- For patients at risk for QT prolongation, assess the QT interval before and after increasing total Austedo® dosage above 24 mg per day

DOSING MODIFICATIONS:

- 1) Total daily dosage of Austedo® should not exceed 36mg in patients receiving strong CYP2D6 inhibitors (e.g. quinidine, paroxetine, fluoxetine and bupropion).
- 2) Total daily dosage of Austedo® should not exceed 36mg in patients who are poor CYP2D6 metabolizers,

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Beneficiary must be 18 years of age or older; **AND**
- Prescriber must submit chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living; **AND**
- Beneficiary must either have a diagnosis of moderate to severe tardive dyskinesia or chorea associated with Huntington's Disease. If has tardive dyskinesia, beneficiary must meet the following DSM-5 criteria:
 - Involuntary athetoid or choreiform movements; **AND**
 - History of treatment with dopamine receptor blocking agent (DRBA) (e.g. antipsychotics or metoclopramide); **AND**
 - Symptom duration lasting longer than 4 to 8 weeks; **AND**
- Beneficiary with chorea associated with Huntington's Disease must not be suicidal or have untreated or inadequately treated depression; **AND**
- Austedo® must be prescribed by a neurologist or psychiatrist; or prescriber has consulted with a neurologist or psychiatrist if symptoms are due to antipsychotic usage or Huntington's disease. Austedo® may also be prescribed by gastroenterology if symptoms are due to metoclopramide usage.; **AND**
- Prescriber must submit the completed Medicaid "Ingrezza® / Austedo® Statement of Medical Necessity" form with the initial request as part of the manual review; **AND**

Updated form



ARRx_SMN_Form_In
grezza_Austedo2.pdf

- For treating Tardive Dyskinesia, prescriber must submit a baseline Abnormal Involuntary Movement Scale (AIMS) form as part of the manual PA review; **AND**
- Female beneficiary must not be pregnant or breastfeeding; **AND**
- If beneficiary has taken benztropine, or any other agent for EPS symptoms, provider must submit data documenting the response to the agent; **AND**
- Beneficiary must not have congenital long QT Syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval and prescriber must provide attestation; **AND**
- If beneficiary takes a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) OR the beneficiary is a poor CYP2D6 metabolizer, maximum daily dose is reduced to 36mg; **AND**
- Beneficiary must not have hepatic impairment and prescriber must provide attestation; **AND**
- Beneficiary must not be taking monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor or reserpine; **AND**
- Provider must provide the Austedo® tapering plan with each PA request until beneficiary reaches a stable, maintenance dose; **AND**
- The initial Austedo® PA will be approved for two (2) months to allow time for titration. Austedo® 6mg can be approved up to a maximum of #240 tablets (8 tablets per day) during the initial two (2) months of treatment for titration. If additional titration time is needed beyond the original two (2) months, another PA with quantity override would be required. Once compliant on a maintenance dose, PAs may be approved for a maximum of 6 months.

DENIAL CRITERIA:

- Beneficiary is < 18 years of age; **OR**
- Beneficiary is not compliant on prescribed dose after previous approval; **OR**
- Prescriber requests dose > 48mg/ day; **OR**
- Prescriber requests a dose > 36mg/ day for beneficiaries taking a strong CYP2D6 inhibitor or is a poor CYP2D6 metabolizer; **OR**
- Beneficiary does not have an improvement from baseline AIMS score or a positive clinical response to therapy on renewal request; **OR**
- Beneficiary with a diagnosis of chorea associated with Huntington's Disease is suicidal or has untreated or inadequately treated depression; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary has congenital long QT Syndrome or cardiac arrhythmias associated with prolonged QT interval; **OR**
- Beneficiary has documented hepatic impairment; **OR**
- Beneficiary develops Neuroleptic Malignant Syndrome; **OR**
- Beneficiary takes reserpine, MAOIs or any other VMAT2 inhibitor; **OR**
- Beneficiary does not meet the approval criteria

CONTINUATION CRITERIA:

- Beneficiary must be compliant on prescribed dose; **AND**
- Prescriber must submit current chart notes; **AND**

- Prescriber must provide an updated AIMS form and documentation of clinical response to therapy every 6 months; **AND**
- Beneficiary must show an improvement from baseline AIMS score and/or have a positive clinical response to therapy; **AND**
- Beneficiary must continue to meet approval criteria.

QUANTITY EDITS:

6mg tablets = #60 per 30 days (The initial PA will be approved for a maximum of #240 tablets for titration for 2 months only.)

9mg tablets = #120 per 30 days

12mg tablets = #120 per 30 days

EFFECTIVE IMMEDIATELY:

4) Hemlibra® (emicizumab) 30mg/mL, 60mg/0.4mL, 105mg/0.7mL and 150mg/mL subcutaneous injections

INDICATION:

Hemlibra® is a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors. (Previously indicated for patients **with factor VIII inhibitors only**)

DOSING:

The recommended loading dose is 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by a maintenance dose of:

- 1.5 mg/kg once every week, or
- 3 mg/kg once every two weeks, or
- 6 mg/kg once every four weeks.

The selection of a maintenance dose should be based on healthcare provider preference with consideration of regimens that may increase patient adherence. Discontinue the prophylactic use of bypassing agents the day before starting Hemlibra® prophylaxis. The prophylactic use of factor VIII (FVIII) products may be continued during the first week of Hemlibra® prophylaxis.

Missed Dose

If a dose of Hemlibra® is missed administer as soon as possible and then resume usual dosing schedule. Do not administer two doses on the same day to make up for a missed dose

APPROVAL CRITERIA:

From clinical trial NCT02622321, NCT03020160 and NCT02795767 (HAVEN 1, 2, AND 4)

APPROVAL CRITERIA for Hemophilia A WITH Inhibitors:

- Manual review on a case-by-case basis; **AND**
- Beneficiary must have a diagnosis of congenital hemophilia A with high factor VIII inhibitor titer (≥ 5 Bethesda units per mL (BU)); **AND**
- Documentation Hemlibra® is prescribed for the prevention of bleeding episodes; **AND**
- Provide documentation of previous treatment with episodic and prophylactic bypassing agents for at least the last 24 weeks; **AND**
- Provide chart notes for the last 24 weeks and current labs (CBCs and LFTs); **AND**
- Provide clarification that beneficiary will NOT be receiving concurrent prophylactic treatment with bypassing agents or have ongoing/plan to receive immune tolerance

- induction therapy while taking Hemlibra®. Beneficiary may receive episodic treatment with bypassing agents as need for breakthrough bleeding episodes; **AND**
- Provide beneficiary's bleed history for the last 24 weeks and include description of bleed episode and treatment required; **AND**
 - Did beneficiary have ≥ 6 bleeds on episodic treatment only? **OR**
 - Did beneficiary have ≥ 2 bleeds on prophylactic treatment with bypassing agents?
 - Provide documentation of treatment plan concerning episodic products (Feiba or NovoSeven); **AND**
 - Provide beneficiary's weight with each PA request; **AND**
 - Provide a letter of medical necessity outlining rationale for changing therapy from existing treatment; **AND**
 - Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis (see continuation below).

From clinical trial NCT02847637 and NCT03020160 (HAVEN 3 AND 4)
APPROVAL CRITERIA for Hemophilia A WITHOUT Inhibitors:

- Manual review on a case-by-case basis; **AND**
- Beneficiary must have a diagnosis of severe congenital hemophilia A with endogenous factor VIII levels $<1\%$ of normal OR documentation of ≥ 5 bleeding episodes in the last 24 weeks; **AND**
- Documentation Hemlibra® is prescribed for the prevention of bleeding episodes; **AND**
- Provide documentation of the details of previous prophylactic and/or episodic FVIII treatment. Beneficiary must have received episodic or prophylactic factor VIII infusions for at least 24 weeks; **AND**
- Provide beneficiary's bleed history for the last 24 weeks and include description of bleed episode and treatment required; **AND**
- Provide chart notes for the last 24 weeks and current labs (CBCs and LFTs); **AND**
- Provide clarification that beneficiary will discontinue prophylaxis factor VIII; **AND**
- Provide documentation of treatment plan concerning episodic factor products; **AND**
- Provide beneficiary's weight with each PA request; **AND**
- Provide letter of medical necessity outlining rationale for changing therapy from existing treatment including increasing the frequency of factor VIII use; **AND**
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis (see continuation below).

DENIAL CRITERIA:

- Beneficiary does not have a diagnosis of congenital hemophilia A; **OR**
- Beneficiary continues to receive prophylaxis doses (e.g., FVIII, FIX, or bypassing agents); **OR**
- Beneficiary is not compliant on prescribed Hemlibra® dose; **OR**
- Prescriber requests dose above FDA-approved dose or prescribes the use of Hemlibra® for PRN dosing; **OR**
- No positive response in the decrease of bleeding episodes or decrease of episodic agent use.

CONTINUATION CRITERIA:

- Provide all of beneficiary's chart notes and labs since previous approval; **AND**
- Provide beneficiary's current weight; **AND**

- Documentation of compliance on Hemlibra®; **AND**
- Provide documentation of beneficiary's bleeding episodes including frequency, drug used and dose since previous approval; **AND**
- If beneficiary continues to need episodic treatment and pharmacy records indicate that prescriptions are billed monthly, provide the medical necessity to continue Hemlibra®; **AND**
- Continued renewal requires a positive response to Hemlibra® (decrease in bleeding episodes and/or decrease in episodic agent requirements); **AND**
- Provide dosing/frequency requirements of Hemlibra® with each renewal request; **AND**
- Once beneficiary is stable on Hemlibra® and indicates a positive response, PA's may be approved for 3 months at a time.

QUANTITY EDITS:

None since weight-based dosing

5) Cablivi® (caplacizumab-yhdp) intravenous or subcutaneous injection

INDICATION:

Cablivi® is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange (PEX) and immunosuppressive therapy.

Immunosuppressive therapy (corticosteroids or rituximab) stops the immune system from producing new antibodies against ADAMTS13. PEX removes the antibodies that block the ADAMTS13 enzyme and replace the ADAMTS13 enzymes in the blood.

DOSING:

Cablivi® should be administered upon the initiation of plasma exchange therapy. The recommended dose of Cablivi® is as follows:

- First day of treatment: 11 mg bolus intravenous injection at least 15 minutes prior to plasma exchange followed by an 11 mg subcutaneous injection after completion of plasma exchange on day 1.
- Subsequent treatment during daily plasma exchange: 11 mg subcutaneous injection once daily following plasma exchange.
- Treatment after the plasma exchange period: 11 mg subcutaneous injection once daily for 30 days beyond the last plasma exchange.
- If after initial treatment course, sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days.
- Discontinue Cablivi® if the patient experiences more than 2 recurrences of aTTP, while on Cablivi®.

The first dose should be administered by a healthcare provider as a bolus intravenous injection. Administer subsequent doses subcutaneously in the abdomen.

*Denotes pulled from clinical trial NCT02553317 (HERCULES)

APPROVAL CRITERIA:

- Must be ≥ 18 years of age; **AND**
- Beneficiary has a clinical diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) (initial or recurrent) ; **AND**
- Provide the medical necessity over high dose glucocorticoids and rituximab with PEX; **AND**
- Beneficiary is currently taking immunosuppressive therapy; **AND**

- Beneficiary has initiated plasma exchange; **AND**
- Provide chart notes/hospitalization notes with treatment plan; **AND**
- Provide current labs with minimum of the following: CBCs with platelets, LFTs, and ADAMTS13 activity level (may not have immediately but should be drawn and pending results); **AND**
- Provide treatment plan if beneficiary has clinically significant bleeding; **AND**
- Beneficiary should not be pregnant or breastfeeding (until at least 2 months after last dose)✳ ; **AND**
- Beneficiary considered high-risk and hospitalized and has at least one of the following (per UpToDate):
 - Neurologic abnormalities
 - Decreased level of consciousness
 - Elevated serum troponin level
 - Other signs of critical illness
- Approve 1 month at a time (max quantity would be 58 plus number of days getting PEX)

DENIAL CRITERIA:

- Diagnosed with congenital thrombotic thrombocytopenic purpura or has other cause for thrombocytopenia; **OR**
- Pregnant or breastfeeding✳ ; **OR**
- Not receiving PEX or immunosuppressive therapy; **OR**
- Beneficiary is classified as standard risk and responds to PEX/glucocorticoids
- Interrupt treatment if clinically significant bleeding occurs✳ ; **OR**
- Concomitant use with anticoagulant?? (or require INR/PT and close monitoring); **OR**
- Discontinue if more than 2 recurrences of aTTP while on Cablivi®; **OR**
- ADAMTS13 activity level >10%; **OR**
- Platelet count $\geq 100 \times 10^9/L$ ✳

CONTINUATION CRITERIA:

- Patients with suppressed ADAMTS13 enzyme activity level indicates persistent underlying disease after initial treatment course. Treatment may be extended to a total of 28 extra days. Discontinue treatment if ADAMTS13 activity is above 20-30% (per UpToDate) ; **AND**
- Provide current chart notes and previously requested labs; **AND**
- Verify last date of PEX; **AND**
- Documentation of compliance with Cablivi® and immunosuppressive therapy.

QUANTITY EDITS:

Maximum of 58 days after plasma exchange is complete.

6) [Piqray® \(alpelisib\) 50mg, 150mg and 200mg tablets](#)

INDICATION:

Piqray® is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

Select patients for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer with Piqray®, based on the presence of one or more PIK3CA mutations in tumor tissue or plasma specimens. If no mutation is detected in a plasma specimen, test tumor tissue. Information on FDA-approved tests for the detection of PIK3CA mutations in breast cancer is available at: [HTTP://WWW.FDA.GOV/COMPANIONDIAGNOSTICS](http://www.fda.gov/companiondiagnostics).

DOSING:

The recommended dose of Piqray® is 300 mg (two 150 mg film-coated tablets) taken orally, once daily, with food. Continue treatment until disease progression or unacceptable toxicity occurs. When given with Piqray®, the recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29, and once monthly thereafter.

DOSING MODIFICATIONS:

PIQRAY® Dose Level	Dose and Schedule	Number and Strength of Tablets
Starting dose	300 mg once daily	Two 150 mg tablets
First-dose reduction	250 mg once daily	One 200 mg tablet and one 50 mg tablet
Second-dose reduction	200 mg once daily	One 200 mg tablet

FURTHER DOSING MODIFICATIONS:

- 1) Hyperglycemic patients (64%) are complicated and dependent upon blood glucose levels and anti-diabetic usage. If FPG is confirmed at > 500 mg/dL or 27.8 mmol/L, permanently discontinue Piqray® treatment.
- 2) Grade 3 rash requires interruption of therapy until ≤ Grade 1 along with topical/systemic corticosteroid and oral antihistamine treatment. Grade 4 rash requires permanent discontinuation.
- 3) Patients with ≥ Grade 2 diarrhea (58% require treatment) requires interruption of therapy until ≤ Grade 1.
- 4) All other toxicities including Grade 2 and 3 pancreatitis and Grade 2 bilirubin elevation require interruption in therapy. Grade 4 toxicity requires discontinuation.

*Denotes pulled from clinical trial NCT02437318 (SOLAR-1)

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Must be ≥ 18 years of age; **AND**
- If woman, provide documentation that postmenopausal; **AND**
- Provide documentation that beneficiary has HR positive and HER2 negative, PIK3CA-mutated, advanced or metastatic breast cancer; **AND**
- Beneficiary has relapsed after previous treatment with documented evidence of progression; **AND**
- Provide CBCs, BMPs, HbA1c, LFTs; **AND**
- Provide documentation of previous or current endocrine-based therapy—requires current fulvestrant use; **AND**
- Provide documentation that patient was advised to start antidiarrheal treatment and educated on the symptoms of hyperglycemia and educated about signs of severe cutaneous reactions; **AND**
- Beneficiary has either measurable disease or at least one predominantly lytic bone lesion present*; **AND**

- ECOG score ≤2; **AND**
- Initial approval for 1 month due to significant adverse reaction potential.

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- History of or current diagnosis of severe cutaneous reactions including Stevens-Johnson Syndrome, Erythema Multiforme or Toxic Epidermal Necrolysis; **OR**
- Beneficiary has inflammatory breast cancer*; **OR**
- Beneficiary has diabetes mellitus Type 1 or uncontrolled Type 2*; **OR**
- Beneficiary has Child-Pugh score B or C*; **OR**
- Beneficiary has history of acute pancreatitis within 1 year of screening or past history of chronic pancreatitis*; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary taking strong CYP3A4 inducers

CONTINUATION CRITERIA:

- Provide current chart notes with documentation of response to therapy; **AND**
- Provide current labs including HbA1c obtained every 3 months; FPG should be checked once every week for the first 2 weeks then at least once every 4 weeks; **AND**
- Verify that beneficiary is not experiencing intolerable toxicity including severe cutaneous reactions, severe hyperglycemia and diarrhea

QUANTITY EDITS:

200mg/day pack #28/28 days
 250mg/day pack #56/28 days
 300mg/day pack #56/28 days

7) [Xpovio™ \(selinexor\) 20mg tablets](#)

INDICATION:

Xpovio™ is a nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Benefit-risk ratio appeared to be greater in this more heavily pretreated population than in the overall trial population.

DOSING:

The recommended starting dosage of Xpovio™ is 80 mg (four 20 mg tablets) taken orally on Days 1 and 3 of each week until disease progression or unacceptable toxicity. The recommended starting dosage of dexamethasone is 20 mg taken orally with each dose of Xpovio™ on Days 1 and 3 of each week.

DOSING MODIFICATIONS:

Recommended Starting Dosage	First Reduction	Second Reduction	Third Reduction
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80 mg Days 1 and 3 of each week (160 mg total per week)	100 mg once weekly	80 mg once weekly	60 mg once weekly
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FURTHER DOSING MODIFICATIONS:

- 1) Thrombocytopenia—severe in 61% of patients; dose change for any patient with platelets <75,000
- 2) Neutropenia—severe in 21% of patients; dose change for absolute neutrophil count $\leq 1.0 \times 10^9/L$
- 3) Anemia—dose change for Hb <8 g/dL
- 4) Hyponatremia—severe in 22% of patients; dose change for sodium ≤ 130 mmol/L
- 5) Fatigue—dose change for Grade 2 >7 days or Grade 3
- 6) Nausea and Vomiting—severe nausea in 9% of patients; severe vomiting in 4% of patients; dose change for Grade 3
- 7) Diarrhea—severe in 6% of patients; dose change 2nd episode of Grade 2 or Grade 3
- 8) Weight Loss and Anorexia—grade 3 anorexia in 5% of patients; dose change if $\geq 10\%$ weight loss or anorexia with weight loss
- 9) Other Non-Hematologic Adverse Reactions—dose change for Grade 3 or 4

Denotes pulled from clinical trial NCT02336815 (STORM)*APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary must have diagnosis of relapsed or refractory multiple myeloma; **AND**
- Beneficiary must have received at least four prior therapies; refractory to at least 2 proteasome inhibitors (e.g., bortezomib, ixazomib and carfilzomib), at least two immunomodulatory agents (e.g., lenalidomide, pomalidomide and thalidomide), and an anti-CD38 monoclonal antibody (e.g. daratumumab); **AND**
- Beneficiary must be prescribed concomitant dexamethasone; **AND**
- Provider must submit chart notes with documentation of previous treatment; **AND**
- Provide current labs including complete blood count and standard blood chemistry along with body weight as a baseline. Monitor platelet, sodium and neutrophil counts at baseline, during treatment, and as clinically indicated. Monitor more frequently during the first two months of treatment; **AND**
- Provide treatment plan for potential nausea and dehydration; **AND**
- Beneficiary must not be pregnant or breastfeeding; **AND**
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

DENIAL CRITERIA:

- Beneficiary does not meet the approval criteria; **OR**
- Beneficiary can not tolerate the minimum dose of 60mg per week; **OR**
- Beneficiary has active smoldering multiple myeloma*; **OR**
- Beneficiary has active plasma cell leukemia*; **OR**
- Beneficiary has documented systemic amyloid light chain amyloidosis*; **OR**
- Beneficiary has active CNS multiple myeloma*; **OR**
- Adverse effects that require dose modifications do not meet recommendations; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary is not prescribed dexamethasone to take concomitantly.

CONTINUATION CRITERIA:

- Provider must submit current chart notes with documentation of response to therapy; **AND**
- Provide at a minimum the following labs: basic metabolic panel (especially need sodium level), CBC with differential (especially need neutrophil and platelet count); **AND**
- Current beneficiary weight; **AND**
- Documentation of dose requested for renewal; **AND**
- Once stable, PA's may be approved 3 months at a time.

QUANTITY EDITS:

60mg once weekly= 12 tablets per 28 days
80mg once weekly= 16 tablets per 28 days
100mg once weekly= 20 tablets per 28 days
80mg twice weekly= 32 tablets per 28 days

8) Iressa® (gefitinib) 250mg tablets

INDICATION:

Iressa® is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

DOSING:

The recommended dose of Iressa® is 250 mg orally once daily with or without food until disease progression or unacceptable toxicity. Do not take a missed dose within 12 hours of the next dose.

Administration to Patients Who Have Difficulty Swallowing Solids

Immerse Iressa® tablets in 4 to 8 ounces of water by dropping the tablet in water and stir for approximately 15 minutes. Immediately drink the liquid or administer through a naso-gastric tube. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube

DOSING MODIFICATION:

1) Adverse reactions

Withhold Iressa® (for up to 14 days) for any of the following:

- Acute onset or worsening of pulmonary symptoms (dyspnea, cough, fever)
- NCI CTCAE Grade 2 or higher in ALT and/or AST elevations
- NCI CTCAE Grade 3 or higher diarrhea
- Signs and symptoms of severe or worsening ocular disorders including keratitis
- NCI CTCAE Grade 3 or higher skin reactions

Resume treatment with Iressa® when the adverse reaction fully resolves or improves to NCI CTCAE Grade 1.

Permanently discontinue Iressa® for:

- Confirmed interstitial lung disease (ILD)
- Severe hepatic impairment
- Gastrointestinal perforation
- Persistent ulcerative keratitis

2) Drug interactions

Strong CYP3A4 Inducers

Increase Iressa® to 500 mg daily in the absence of severe adverse drug reaction, and resume Iressa® at 250 mg seven days after discontinuation of the strong CYP3A4 inducer.

***Denotes pulled from clinical trial NCT00770588**

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary has diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations; **AND**
- Verify if beneficiary takes strong CYP3A4 inducers since requires higher dose (e.g., rifampicin, phenytoin or tricyclic antidepressant); **AND**
- Verify if beneficiary requires proton pump inhibitors due to decrease plasma concentration of Iressa®; **AND**
- Beneficiary should not be pregnant or breastfeeding; **AND**
- ECOG score ≤ 2; **AND**
- Provide beneficiary's current chart notes; **AND**
- Provide beneficiary's current labs including CBC and LFTs; **AND**
- Initial PA duration decided on a case-by-case basis

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- Beneficiary has EGFR mutation other than exon 19 deletions or exon 21 (L858R) substitution mutations; **OR**
- Beneficiary is pregnant and/or breastfeeding; **OR**
- Beneficiary has confirmed diagnosis of interstitial lung disease; **OR**
- Beneficiary has confirmed gastrointestinal perforation; **OR**
- Beneficiary has severe hepatic impairment; **OR**
- Beneficiary has persistent ulcerative keratitis; **OR**
- Beneficiary has concomitant proton pump inhibitor usage; **OR**
- Beneficiary has severe bullous blistering or exfoliating conditions or has a history of toxic epidermal necrolysis, Stevens Johnson syndrome or erythema multiforme

CONTINUATION CRITERIA:

- Beneficiary has not progressed or had intolerable toxicity; **AND**
- Provider must submit current chart notes and labs; **AND**
- Provider must submit documentation that beneficiary does not have a denial criteria

QUANTITY EDITS:

#30 per 30 days

9) **Nubeqa™ (darolutamide) 300mg tablets**

INDICATION:

Nubeqa™ is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. (category 1)

DOSING:

Nubeqa™ 600 mg, (two 300 mg tablets) administered orally twice daily. Swallow tablets whole. Take Nubeqa™ with food. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

DOSING MODIFICATION:

- 1) Grade 3 Toxicity
If a patient experiences a greater than or equal to Grade 3 toxicity or an intolerable adverse reaction, withhold dosing or reduce to 300 mg twice daily until symptoms improve. Then the treatment may be resumed at a dose of 600 mg twice daily.

Dose reduction below 300 mg twice daily is not recommended.
- 2) Severe Renal Impairment
For patients with severe renal impairment (eGFR 15–29 mL/min/1.73 m²) not receiving hemodialysis, the recommended dose of Nubeqa™ is 300 mg twice daily
- 3) Moderate or Severe Hepatic Impairment
For patients with moderate hepatic impairment (Child-Pugh Class B or C), the recommended dose of Nubeqa™ is 300 mg twice daily

***Denotes pulled from clinical trial NCT02200614 (ARAMIS)**

APPROVAL CRITERIA:

- Manual review on a case-by-case; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary must have the diagnosis of non-metastatic castration-resistant prostate cancer; **AND**
- Provider must submit current chart notes with documentation of previous treatment history; **AND**
- Provider must submit current labs including CBCs, LFTs, renal function, testosterone level, PSA; **AND**
- Beneficiary must also receive a gonadotropin-releasing hormone analog concurrently or have had a bilateral orchiectomy (provide this documentation); **AND**
- Documentation of castrate level of serum testosterone*; **AND**
- ECOG score ≤ 2; **AND**
- Prostate-specific antigen doubling time of ≤ 10 months AND PSA > 2ng/ml*; **AND**
- Provider must attest to counseling sexually active patients that are not surgically sterile to use condoms; **AND**
- PA's may be approved for 3 months at a time

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- History of metastatic disease*; **OR**
- History of the following in the last 6 months: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, CHF NYHA class III or IV*; **OR**
- Beneficiary is currently taking P-gp and strong or moderate CYP3A4 inducers (rifampicin) due to decreased Nubeqa™ levels; **OR**
- Severe renal impairment and moderate hepatic impairment require dose decreases

CONTINUATION CRITERIA:

- Beneficiary is compliant on Nubeqa™ and GnRH analog; **AND**
- Provide current chart notes and previously requested labs; **AND**
- PSA levels remain stable

QUANTITY EDITS:

#120 per 30 days

10) Turalio™ (pexidartinib) 200mg capsules

Turalio™ is a Risk Evaluation and Mitigation Strategy (REMS) drug due to hepatotoxicity.

INDICATION:

Turalio™ is a tyrosine kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

DOSING:

The recommended dosage of Turalio™ is 400 mg taken twice daily on an empty stomach until disease progression or unacceptable toxicity.

DOSING MODIFICATION: (very specific dosing modification requirements for hepatotoxicity)

Dose Reduction	Total Daily Dose	Administration of Total Daily Dose
First	600 mg	200 mg in the morning and 400 mg in the evening
Second	400 mg	200 mg twice daily

Table 1: Recommended Dose Reductions for TURALIO for Adverse Reactions

- 1) Increased ALT and/or AST—withhold and reduce dose if > 3-5 x ULN and < 10 x ULN; above 10 x ULN should be discontinued
- 2) Increased ALP and GGT—discontinue if >2 x ULN
- 3) Increased bilirubin—withhold and reduce dose if total bilirubin > ULN to < 2 x ULN or direct bilirubin > ULN to < 1.5 x ULN; TB > 2 x ULN and DB > 1.5 x ULN should be discontinued
- 4) Mild to severe renal impairment (CrCl 15-89 mL/min) requires dose reduction to 600mg per day

***Denotes pulled from clinical trial NCT02371369 (ENLIVEN)**

APPROVAL CRITERIA:

- Manual review on a case-by-case; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary has a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS)) associated with severe morbidity or functional limitations and not amenable to improvement with surgery; **AND**
- Provide documentation that provider and beneficiary are enrolled in REMS program; **AND**
- Beneficiary should not be pregnant or breastfeeding; **AND**
- Provide beneficiary’s current chart notes with description of current range of motion and treatment history (if applicable); **AND**

- Provide MRI results confirming diagnosis; **AND**
- Provide the medical necessity of Turalio™ over surgery and/or radiation; **AND**
- Provide the following labs:
 - LFTs including ALT/AST, ALP, GGT and bilirubin (labs monitored weekly for first 8 weeks, every 2 weeks for the next month and every 3 months thereafter) ; **AND**
 - Renal function including serum creatinine and BUN; **AND**
 - CBC with differential; **AND**
- Documentation of stable prescription of analgesic regimen which can include opioids, anti-inflammatories or corticosteroids for at least 2 weeks with continued pain and mobility difficulties *; **AND**
- Provider must attest to counseling sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control; **AND**
- Provide physical therapy notes if available; if not receiving PT, provider should explain rationale; **AND**
- PA's approved month-to-month for at least first 3 months to monitor labs

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Discontinue if cannot tolerate dose of 200mg twice daily; **OR**
- Discontinue if the following:
 - ALT and/or AST >10 x ULN
 - ALP and GGT >2 x ULN
 - Total bilirubin ≥2 x ULN or Direct bilirubin >1.5 x ULN
- Concomitant use of proton pump inhibitors; **OR**
- Concomitant use of strong CYP3A inhibitor (e.g., itraconazole) or uridine diphosphoglucuronosyltransferase (UGT) inhibitor (e.g., probenecid)—if unavoidable, reduce Turalio™ dose; **OR**
- Provider or beneficiary are not enrolled in the REMS program; **OR**
- Active or chronic infection with hepatitis C virus, hepatitis B virus or human immunodeficiency virus *

CONTINUATION CRITERIA:

- Beneficiary is compliant on therapy; **AND**
- Provide current chart notes; **AND**
- Provide current labs including LFTs, CBC with differential and renal function; **AND**
- Labs must fall within manufacturer's guidelines for renewal; **AND**
- Provide documentation of response to therapy with decrease in tumor size and/or documentation of improvement in range of motion; **AND**
- Reevaluate for surgery eligibility.

QUANTITY EDITS:

#120 per 30 days

11) Inrebic® (fedratinib hydrochloride) 100mg capsules

INDICATION:

Inrebic® is a kinase inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

DOSING:

The recommended dosage of Inrebic® is 400 mg taken orally once daily for patients with a baseline platelet count of greater than or equal to $50 \times 10^9/L$.

Inrebic® may be taken with or without food. Administration with a high fat meal may reduce the incidence of nausea and vomiting.

DOSING MODIFICATION:

- 1) Reduce Inrebic® dose when administering with strong CYP3A4 inhibitors to 200 mg once daily
- 2) Reduce Inrebic® dose to 200 mg once daily in patients with severe renal impairment (creatinine clearance (CL_{cr}) 15 mL/min to 29 mL/min as estimated by Cockcroft-Gault (C-G) equation).
- 3) Modify dose for hematologic and non-hematologic adverse reactions per Table 1 and Table 2. Discontinue Inrebic® in patients unable to tolerate a dose of 200 mg daily.

Hematologic Adverse Reactions	Dose Reduction
Grade 4 Thrombocytopenia <u>or</u> Grade 3 Thrombocytopenia with active bleeding	Interrupt dose until resolved to Grade 2 or lower or baseline. Restart dose at 100 mg daily below the last given dose.
Grade 4 Neutropenia	Interrupt dose until resolved to Grade 2 or lower or baseline. Restart dose at 100 mg daily below the last given dose.

Table 1 : Dose Modifications for Hematologic Adverse Reactions

Non-hematologic Adverse Reactions	Dose Reduction
Grade 3 or higher Nausea, Vomiting, or Diarrhea not responding to supportive measures within 48 hours	Interrupt dose until resolved to Grade 1 or lower or baseline. Restart dose at 100 mg daily below the last given dose.
Grade 3 or higher ALT, AST, or Bilirubin	Interrupt dose until resolved to Grade 1 or lower or baseline. Restart dose at 100 mg daily below the last given dose. Monitor ALT, AST, and bilirubin (total and direct) more frequently following the dose reduction. If re-occurrence of a Grade 3 or higher elevation, discontinue treatment with INREBIC.
Grade 3 or higher Other Non-hematologic Toxicities	Interrupt dose until resolved to Grade 1 or lower or baseline. Restart dose at 100 mg daily below the last given dose.

Table 2: Dose Modifications for non-Hematologic Adverse Reactions

✱ *Denotes pulled from clinical trial NCT01437787 (JAKARTA)*

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**

- Must be ≥ 18 years of age; **AND**
- Beneficiary has a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF); **AND**
- Provide the following baseline labs:
 - Thiamine (Vitamin B1)
 - CBC with platelets
 - Creatinine and BUN
 - Hepatic panel
 - Amylase and lipase; **AND**
- Beneficiary must have thiamine deficiencies corrected prior to initiating Inrebic®; **AND**
- Beneficiary has an enlarged spleen, palpable at least 5 cm below costal margin *; **AND**
- ECOG score ≤ 2 *; **AND**
- Beneficiary must have at least 2 hydroxyurea drug claims in Medicaid drug history. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant to hydroxyurea; **AND**
- Provider must submit the medical necessity over the use of Jakafi (ruxolitinb); **AND**
- Beneficiary must taper off ruxolitinib prior to initiating Inrebic®; **AND**
- Provider must reduce Inrebic® dose to 200mg once daily if beneficiary has severe renal impairment (CrCl 15mL/min to 29mL/min) ; **AND**
- Initial PA will be for the specific strength required for dose; approval time will be for 1 month.

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- Beneficiary has a platelet count $< 50 \times 10^9 /L$; **OR**
- Beneficiary has thiamine deficiency; **OR**
- Beneficiary has signs of Wernicke's encephalopathy (ataxia, mental status changes and ophthalmoplegia); **OR**
- Beneficiary has had a splenectomy; **OR**
- Beneficiary has previous history of chronic liver disease; **OR**
- Beneficiary does not show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; **OR**
- Continued use of strong and moderate CYP3A4 inducers; **OR**
- Continued use with dual CYP3A4 and CYP2C19 inhibitors; **OR**
- Beneficiary unable to tolerate 200mg daily dose

CONTINUATION CRITERIA:

- Beneficiary must be compliant on therapy; **AND**
- Current chart notes and updated labs (including thiamine, CBC with platelets, creatinine and BUN, hepatic panel and amylase/lipase) must be provided; **AND**
- Labs must follow manufacturer's dosing recommendations; **AND**
- Beneficiary must show positive response to Inrebic® by spleen size reduction or symptom improvement within 6 months of therapy.

QUANTITY EDITS:

#120 per 30 days

12) Nucala® (mepolizumab) 100mg/mL Syringe/Autoinjector

****NUCALA® VIALS** will remain excluded from the pharmacy program as must be administered by a healthcare professional.**

****NUCALA® AUTOINJECTOR/PREFILLED SYRINGES** became available earlier this year for self-administration.**

INDICATION:

Nucala® is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.

DOSING:

- Severe asthma in patients aged 12 years and older: 100 mg administered subcutaneously once every 4 weeks.
- Severe asthma in patients aged 6 to 11 years: 40 mg administered subcutaneously once every 4 weeks.
- EGPA: 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks.

DOSING MODIFICATIONS:

The Nucala® injection prefilled autoinjector and prefilled syringe are only for use in adults and adolescents aged 12 years and older. Patients aged 6 to 11 years require a 40 mg subcutaneous dose which cannot be obtained by the autoinjector/pre-filled syringes. To get this dose, the provider must reconstitute a Nucala® vial and administer 0.4mL from the vial. Since these patients must receive their doses by the healthcare professional, they will be excluded from the use of the autoinjector/prefilled syringes.

***Denotes pulled from clinical trials NCT01000506, NCT01691521, NCT01391508 and NCT02020889**

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Provide the following documentation for review:
 - Current chart notes
 - Documentation of previous therapies tried with response
 - Baseline blood eosinophilic count
 - Baseline Asthma Control Questionnaire (ACQ-5) OR Asthma Quality of Life Questionnaire (AQLQ) scores (adults only)
 - Current Pulmonary Function Test (PFT) results; **AND**
- No therapeutic duplication with any Interleukins (daclizumab, mepolizumab, or others new to the market) or omalizumab; **AND**
- If approved, PA will be for 6 months at a time. Renewal requires documentation of positive response after 6 months.

Criteria specific to Eosinophilic granulomatosis with polyangiitis (EGPA)

- Beneficiary must be ≥18 years of age. (If the indicated ages change, the criteria will reflect that change) ; **AND**

- Beneficiary must be diagnosed with EGPA for at least 6 months based on the presence of asthma plus eosinophilia ($>1.0 \times 10^9/\text{Liter}$ and/or $>10\%$ of leucocytes) ✱;
AND
- Beneficiary has a history of relapsing OR refractory disease with at least one confirmed EGPA relapse within the last 2 years while taking oral corticosteroids ✱;
AND
- Beneficiary must be on a stable dose of oral prednisolone or prednisone of ≥ 7.5 mg/day for at least four (4) weeks ✱; **AND**
- If beneficiary is receiving immunosuppressive therapy (excluding cyclophosphamide), the dosage must be stable for four (4) weeks ✱; **AND**
- Medical necessity over corticosteroids and/or immunosuppressive therapy.

Criteria specific to Asthma:

- Beneficiary must be ≥ 12 years of age (If the indicated ages change, the criteria will reflect the change); **AND**
- Beneficiary must be diagnosed with severe asthma with a history of 2 or more exacerbations in the previous year ✱; **AND**
- Beneficiary must be compliant on at least two (2) asthma maintenance medications for at least one (1) year (one must be an inhaled corticosteroid) ✱; **AND**
- Blood eosinophil count must be ≥ 150 cells/ μL (one trial ≥ 300 cells/ μL) ✱; **AND**
- Pre-bronchodilator FEV1 $< 80\%$ predicted ✱; **AND**
- Provide the medical necessity over the use of omalizumab (Xolair®) and other therapies outlined in treatment guidelines.

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- For asthma patients—noncompliance with two (2) asthma maintenance medications for at least 1 year including inhaled corticosteroid; **OR**
- For EGPA patients—not on a stable oral corticosteroid dose for at least four (4) weeks and/or does not have a history of relapse or refractory disease; **OR**
- Current smoker; **OR**
- Beneficiary takes other Interleukins; **OR**
- Beneficiary has life-threatening EGPA ✱; **OR**
 - Severe alveolar hemorrhage or hemoptysis requiring transfusion or ventilation, or hemoglobin is < 8 g/dL
 - Rapidly progressive glomerulonephritis with creatinine > 2.5 mg/dL
 - Severe cardiac involvement including life-threatening arrhythmia, LVEF $< 20\%$, NUHA Class III/IV or acute myocardial infarction
- Beneficiary has unstable liver disease with presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, varices or cirrhosis ✱
 - ALT ≥ 2 X ULN (≥ 3 X ULN if on methotrexate or azathioprine)
 - AST ≥ 2 X ULN (≥ 3 X ULN if on methotrexate or azathioprine)
 - Alkaline Phosphatase > 2 X ULN
 - Bilirubin > 1.5 X ULN

CONTINUATION CRITERIA:

- Beneficiary must be compliant on injections and maintenance asthma medications;
AND

- Provide current chart notes with documentation of response to therapy after 6 months; **AND**
- Provide current PFTs—must see improvement in FEV₁ over baseline; **AND**
- Beneficiary must show fewer exacerbations requiring hospitalization and/or emergency department visits; **AND**
- Beneficiary must have a decrease in blood eosinophil count; **AND**
- Beneficiary must have a decrease in oral steroid usage for EPGA patients.

QUANTITY EDITS: #3 prefilled syringes/autoinjectors per 28 days

13) Baqsimi™ (glucagon) 3mg powder

INDICATION:

BAQSIMI™ is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and above.

DOSING:

Baqsimi™ is for intranasal use only.

Instruct patients and their caregivers on the signs and symptoms of severe hypoglycemia. Because severe hypoglycemia requires help of others to recover, instruct the patient to inform those around them about Baqsimi™ and its instructions for use. Administer Baqsimi™ as soon as possible when severe hypoglycemia is recognized.

The recommended dose of Baqsimi™ is 3 mg administered as one actuation of the intranasal device into one nostril. If there has been no response after 15 minutes, an additional 3 mg dose of Baqsimi™ from a new device may be administered while waiting for emergency assistance.

***Denotes pulled from clinical trial NCT03339453, NCT01994746 and NCT01997411**

APPROVAL CRITERIA:

- Must be ≥ 4 years of age; **AND**
- Must have a diagnosis of Diabetes Mellitus; **AND**
- Provider must submit current chart notes; **AND**
- Beneficiary must require daily insulin use; **AND**
- Provider must submit glucose diary for the last 3 months; **AND**
- Provider a letter of medical necessity for Baqsimi™ over Glucagon injection and other antihypoglycemic agents that become available.

DENIAL CRITERIA:

- Beneficiary does not have Diabetes Mellitus; **OR**
- Beneficiary is not receiving daily insulin*; **OR**
- Beneficiary has a history of pheochromocytoma; **OR**
- Beneficiary has a history of insulinoma.

QUANTITY EDITS: 2 doses per prescription fill

14) Rozlytrek™ (entrectinib) 100mg and 200mg capsules

INDICATION:

Rozlytrek™ is a kinase inhibitor indicated for the treatment of:

- Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS1*-positive.
- Adult and pediatric patients 12 years of age and older with solid tumors that:
 - have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation,
 - are metastatic or where surgical resection is likely to result in severe morbidity, and
 - have progressed following treatment or have no satisfactory alternative therapy.

DOSING:

Adults—

The recommended dosage of Rozlytrek™ is 600 mg orally once daily with or without food until disease progression or unacceptable toxicity.

Pediatrics (12 years and older)—

The recommended dosage of Rozlytrek™ is based on body surface area (BSA) as shown in TABLE 1 below. Take Rozlytrek™ orally once daily with or without food until disease progression or unacceptable toxicity

Body Surface Area (BSA)	Recommended Dosage (Orally once daily)
Greater than 1.50 m ²	600 mg
1.11 to 1.50 m ²	500 mg
0.91 to 1.10 m ²	400 mg

Table 1: Dosing in Pediatric Patients 12 Years and Older (Adolescents)

DOSING MODIFICATIONS:

Action	Adults and Pediatric Patients 12 Years and Older with BSA Greater than 1.50 m ² (Orally once daily)	Pediatric Patients 12 Years and Older with BSA of 1.11 to 1.50 m ² (Orally once daily)	Pediatric Patients 12 Years and Older with BSA of 0.91 to 1.10 m ² (Orally once daily)
First dose reduction	400 mg	400 mg	300 mg
Second dose reduction*	200 mg	200 mg	200 mg

- 1) **Congestive Heart Failure**—Grade 2 or 3 withhold and reduce dose; Grade 4 discontinue
- 2) **Central Nervous System Effects**—Grade 3 withhold and reduce dose; Grade 4 discontinue
- 3) **Hepatotoxicity**—Grade 3 withhold and resume at same dose if Grade 1 within 4 weeks and discontinue if does not resolve in 4 weeks; Grade 4 withhold and reduce dose if Grade 1 within 4 weeks and discontinue if does not resolve in 4 weeks; permanently discontinue if ALT or AST >3 X ULN with concurrent total bilirubin >1.5 X ULN
- 4) **Hyperuricemia**—Symptomatic or Grade 4 initiate urate-lowering med, withhold and resume at same or reduced dose

- 5) **QT Interval Prolongation**—QTc >500ms withhold until recovers to baseline, resume at same dose if corrected cause or at lower dose if cause not identified; Discontinue for Torsade de pointes, polymorphic ventricular tachycardia or symptoms of severe arrhythmia
- 6) **Vision Disorders**—Grade ≥ 2 withhold and resume same dose or reduced dose when stabilized
- 7) **Anemia or Neutropenia**—Grade 3 or 4 withhold until \leq Grade 2 and resume at same dose or reduced dose
- 8) **Grade 3 or 4 Relevant Reactions**—withhold until Grade 1 or baseline and resume if resolved within 4 weeks; discontinue if not resolved in 4 weeks
- 9) **Use of moderate and severe CYP3A Inhibitors if must take concomitantly**
 - a. Moderate inhibitor—dose of 200mg once daily
 - b. Strong inhibitor—dose of 100mg once daily

***Denotes pulled from clinical trial NCT02097810 (STARTRK-1) AND NCT02568267 (STARTRK-2)**

APPROVAL CRITERIA:

- Manual review on a case-by-case; **AND**
- Must be ≥ 18 years of age for NSCLC diagnosis and ≥ 12 years of age for Solid Tumors diagnosis; **AND**
- Beneficiary must have a diagnosis of either ROS1-Positive Non-Small Cell Lung Cancer **OR** neurotrophic receptor tyrosine kinase (NTRK) Gene Fusion-Positive Solid Tumors (sarcoma, lung cancer, salivary gland tumor, secretory breast cancer, thyroid cancer and colorectal cancer); **AND**
- Beneficiaries with diagnosis of NTRK Gene Fusion-Positive Solid Tumors must have one of the following:
 - have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation,
 - are metastatic or where surgical resection is likely to result in severe morbidity,
 - have either progressed following treatment or have no satisfactory alternative therapy.
- Provider must submit histologically or cytologically confirmed diagnosis of NTRK1, NTRK2, NTRK3, ROS1 or ALK molecular alteration by using tests such as, next generation sequencing (NGS) or fluorescence in situ hybridization (FISH)*; **AND**
- ECOG ≤ 2 *; **AND**
- Provider must submit current chart notes and documentation of previous treatment (if applicable); **AND**
- Provide current body surface area (BSA) for pediatric patients to adequately verify dosing; **AND**
- Provide current labs including: **AND**
 - Liver Function Tests (LFTs) (monitor every 2 weeks for first month, then monthly)
 - Baseline serum uric acid levels (monitor periodically)
 - Complete Blood Count (CBC) with differential
 - Basic Metabolic Panel (BMP)
- Provide ECG baseline with documentation of QTcF and baseline LVEF; **AND**
- Provider must attest to counseling sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control; **AND**
- Initial PA approve 1 month to monitor for adverse reactions

DENIAL CRITERIA:

- Beneficiary does not meet approval criteria
- Beneficiary has symptomatic CHF, myocardial infarction, unstable angina, or coronary artery bypass graft within 3 months* ; **OR**
- LVEF \leq 50%* ; **OR**
- Beneficiary has risk factors for torsade de pointes* ; **OR**
- Beneficiary has known interstitial lung disease, interstitial fibrosis or history of tyrosine kinase inhibitor-induced pneumonitis* ; **OR**
- Beneficiary has a diagnosis of torsade de pointes, polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary has hepatotoxicity with ALT or AST >3 X ULN with concurrent total bilirubin >1.5 X ULN (in absence of cholestasis or hemolysis); **OR**
- Beneficiary has Grade 4 central nervous system effects; **OR**
- Beneficiary requires moderate or strong CYP3A inhibitors. If requires coadministration, reduce Rozlytrek™ dose and provide documentation of monitoring adverse reactions; **OR**
- Beneficiary requires moderate or strong CYP3A4 inducers as Rozlytrek™ plasma concentrations are decreased; **OR**
- Beneficiary requires another medication that can prolong QT/QTc intervals

CONTINUATION CRITERIA:

- Beneficiary is compliant with therapy; **AND**
- Beneficiary has adverse reactions within recommended dosing parameters; **AND**
- Provider must submit current chart notes with response to therapy with tolerability; **AND**
- Provide current labs including LFTs, serum uric acid levels if indicated, CBC with differential and BMP

QUANTITY EDITS:

100mg capsules -- #30 per 30 days
200mg capsules -- #90 per 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

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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.