ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Pharmacy Program

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

MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: February 24, 2021

SUBJ: **AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board January 20, 2021 meeting for the following: Manual review criteria for: Isotretinoin, GnRH Receptor Antagonists (Orilissa® and Oriahnn™), Thrombopoiesis Stimulating Proteins (Promacta®, Mulpleta®, Doptelet®, and Tavalisse™), Immunomodulators for Asthma (Fasenra®, Dupixent®, Xolair®, and Nucala®), Xpovio® (Selinexor), Gavreto™ (pralsetinib), Ongentys™ (opicapone), Onureg® (azacitidine), and Zokinvy (lonafarnib).**

Preferred Drug List (PDL) therapeutic classes from the February 10, 2021 Drug Review Committee Meeting for the following: Anticoagulants, Antihyperuricemics, Estrogen Agents, GI Motility Agents, and Hepatitis C Agents

Table of Contents

I. ANNOUNCEMENTS

A. ADHD UPDATE REMINDER

As of 2/10/2021, the point-of-sale (POS) edits for ADHD medications have changed.

1) Recipients ≥ 19 years of age require a prior authorization request and a completed CII stimulant form. https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_SMN_Adult_C-II_Stimulant.pdf
2) Recipients < 6 years of age require a prior authorization request for all CII stimulants and atomoxetine.
3) A billed diagnosis of ADHD in the last 2 years is required for children 6-18 years of age. If no ADHD diagnosis is billed, a prior authorization request is required.
4) Atomoxetine will require a billed diagnosis of ADHD for children and adults in the last 2 years.

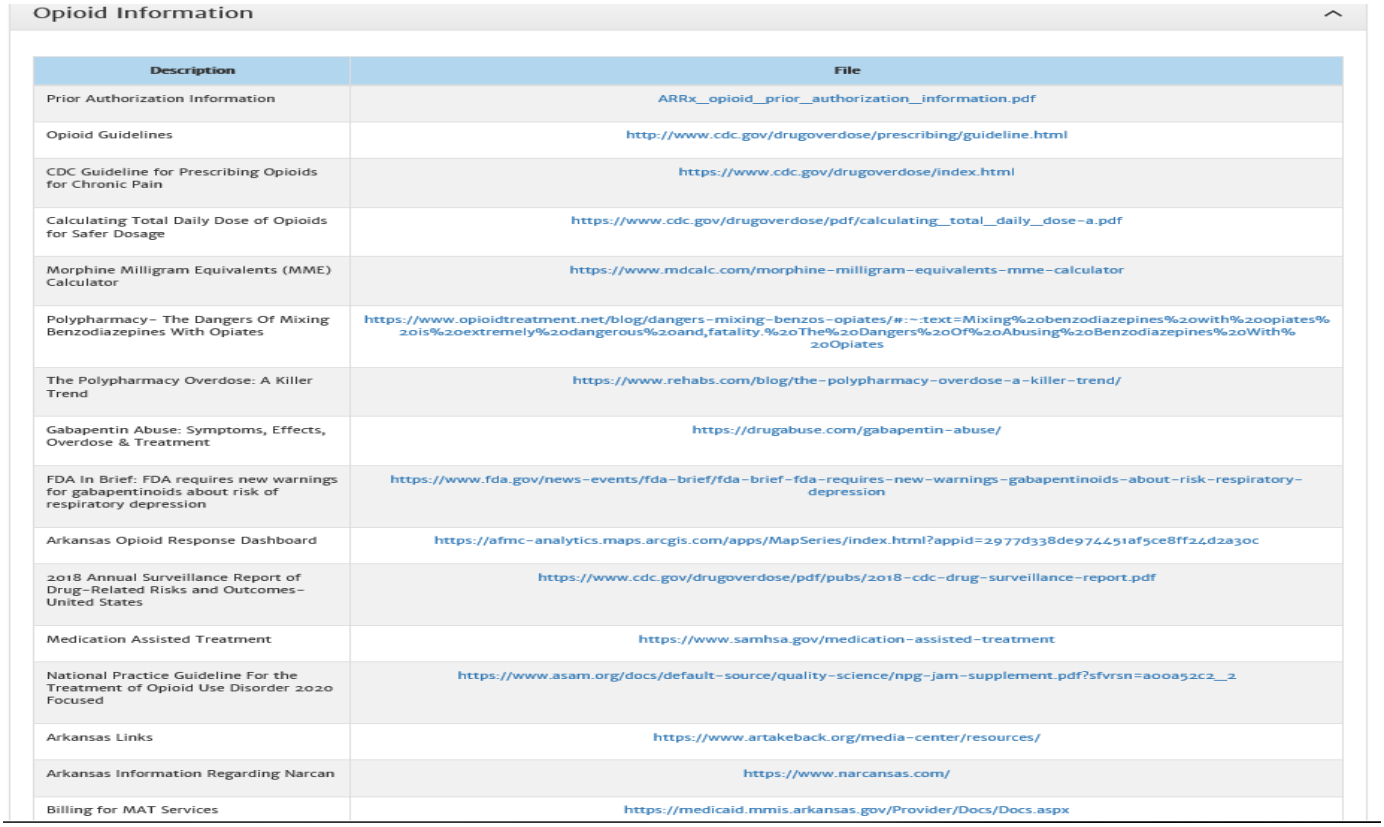
B. NEW PLAN PREFERRED BRAND PRODUCTS

There are 2 products that have recently been released with generic alternatives. Based on NADAC and rebate information, the decision was made to require the following products as brand preferred over the generic.

a. Amitiza® (lubiprostone)
b. Zomig® Nasal Spray (zolmitriptan)

C. OPIOID INFORMATION ON THE MAGELLAN WEBSITE

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



Opioid Information

Description	File
Prior Authorization Information	ARRx_opioid_prior_authorization_information.pdf
Opioid Guidelines	http://www.cdc.gov/drugoverdose/prescribing/guideline.html
CDC Guideline for Prescribing Opioids for Chronic Pain	https://www.cdc.gov/drugoverdose/index.html
Calculating Total Daily Dose of Opioids for Safer Dosage	https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
Morphine Milligram Equivalents (MME) Calculator	https://www.mdcalc.com/morphine-milligram-equivalents-mme-calculator
Polypharmacy- The Dangers Of Mixing Benzodiazepines With Opiates	https://www.opioidtreatment.net/blog/dangers-mixing-benzos-opiates/#:~:text=Mixing%20benzodiazepines%20with%20opiates%20is%20extremely%20dangerous%20and,fatality.%20The%20Dangers%20Of%20Abusing%20Benzodiazepines%20With%20Opiates
The Polypharmacy Overdose: A Killer Trend	https://www.rehabs.com/blog/the-polypharmacy-overdose-a-killer-trend/
Gabapentin Abuse: Symptoms, Effects, Overdose & Treatment	https://drugabuse.com/gabapentin-abuse/
FDA In Brief: FDA requires new warnings for gabapentinoids about risk of respiratory depression	https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-new-warnings-gabapentinoids-about-risk-respiratory-depression
Arkansas Opioid Response Dashboard	https://afmc-analytics.maps.arcgis.com/apps/MapSeries/index.html?appid=2977d338de974451af5ce8ff24d2a30c
2018 Annual Surveillance Report of Drug-Related Risks and Outcomes-United States	https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf
Medication Assisted Treatment	https://www.samhsa.gov/medication-assisted-treatment
National Practice Guideline For the Treatment of Opioid Use Disorder 2020 Focused	https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2
Arkansas Links	https://www.artakeback.org/media-center/resources/
Arkansas Information Regarding Narcan	https://www.narcansas.com/
Billing for MAT Services	https://medicaid.mmis.arkansas.gov/Provider/Docs/Docs.aspx

D. HEPATITIS C TREATMENT INFORMATION

Educational information on treating Hepatitis C along with treatment consultations may be obtained through the Clinician Consultation Center.

1) Link for the Clinician Consultation Center—http://www.hepcap.org/hepatitis-c-consultation-warmline/
2) Hepatitis C Warmline for phone consultation—(844) HEP-INFO or (844) 437-4636

The clinical consultation staff may give advice on any of the following topics:

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

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

E. EARLY REFILL EDIT AND REFILL TOO SOON LOGIC

Reinstatement of EARLY REFILL (ER) EDIT and REFILL TOO SOON (RTS) LOGIC for all non-controlled drugs: Beginning March 23, 2020, due to the COVID-19 emergency, Arkansas Medicaid POS pharmacy providers have been allowed to bypass the early refill ProDUR alert for non-controlled prescriptions. Currently, this change allows the pharmacy provider to enter an override for an early refill DUE alert. The claim will then pay at Point-of-Sale (POS) as long as all additional criteria for that drug is met. In addition, on March 23, 2020, the update to the POS system also included the removal of the "Refill Too Soon" Accumulation Logic from all non-controlled medications. The Refill Too Soon Accumulation Logic removed the requirement to allow an accumulation of up to 12 days of non-controlled medications per 186 days.

Once the Governor's declaration of public health emergency ends for the COVID-19 outbreak, the early refill logic edits will be reinstated. Providers can expect a 30-day notice before the edits are implemented.

To ensure quality and consistency of care to Medicaid clients, DMS will coordinate with the Office of the Medicaid Inspector General (OMIG) to conduct retrospective reviews and audits of early refills dispensed during this time. Please keep all records of services as required by Medicaid physician billing and telemedicine rules.

F. VACCINE/IMMUNIZATION BILLING

In response to the COVID-19 outbreak in Arkansas and consistent with CMS's anticipated coverage of vaccination administration, DMS is covering COVID-19 Vaccination provided by:

- Physicians
- Nurse Practitioners
- Nurse Midwives
- FQHCs
- RHCs
- Pharmacies who are enrolled to provide vaccines
- ADH
- Hospitals (outpatient)

Initially, the vaccine is being provided at no cost to the providers who can administer the vaccine, but administration of the vaccine will be compensated. **The following codes and rates will be available for billing once that vaccine is distributed. These rates and codes will be available through the public health emergency.**

Code	Short Description	Labeler Name	Fee
91300	SARSCOV2 VAC 30MCG/0.3ML IM	Pfizer	$.01

0001A	ADM SARSCOV2 30MCG/0.3ML 1st	Pfizer	$16.94
0002A	ADM SARSCOV2 30MCG/0.3ML 2nd	Pfizer	$28.39
91301	SARSCOV2 VAC 100MCG/0.5ML IM	Moderna	$.01
0011A	ADM SARSCOV2 100MCG/0.5ML 1st	Moderna	$16.94
0012A	ADM SARSCOV2 100MCG/0.5ML 2nd	Moderna	$28.39

Effective July 1, 2020, Arkansas Medicaid will pay $15.45 for the administration of an influenza immunization. A rate of $13.14 will be paid for the administration of other Medicaid payable vaccines. The existing rates for Vaccines For Children (VFC) and SCHIP vaccines will be adjusted to account for this rate increase.

For adult vaccines (ages 18 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:

G0008 – Influenza immunization

90471 – First vaccine administered

90472 – Subsequent vaccines administered

The **Injection administration code, T1502** will continue to be payable for beneficiaries of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only.

If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211.

Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website: https://medicaid.mmis.arkansas.gov/Provider/Docs/Docs.aspx.

If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy: https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/

https://humanservices.arkansas.gov/
https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/

EFFECTIVE APRIL 1, 2021:

II. PREFERRED DRUG LIST (PDL):

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

1) ANTICOAGULANTS

PREFERRED AGENTS

- ELIQUIS® tablet (apixiban)
- ENOXAPARIN vial or syringe (generic for Lovenox®)
- PRADAXA® capsule (dabigatran)
- WARFARIN tablet (generic for Coumadin®)
- XARELTO® tablet (rivaroxaban)

Approval criteria
- No therapeutic duplication allowed between different strengths of the same anticoagulant; **AND**
- One (1) therapeutic duplication with overlapping days' supply will be allowed once per 186 days for an inferred change in therapy between a preferred anticoagulant; **AND**
- The claims cannot have the same date of service.

Additional criteria
Quantity limits apply

NONPREFERRED AGENTS
- ARIXTRA® injection (fondaparinux)
- COUMADIN® tablet (warfarin)
- FONDAPARINUX injection (generic for Arixtra®)
- FRAGMIN® injection (dalteparin)
- LOVENOX® injection (enoxaparin)
- SAVAYSA® tablet (edoxaban)

2) ANTIHYPERURICEMICS

PREFERRED AGENTS
- ALLOPURINOL tablet (generic for Zyloprim®)
- **COLCHICINE tablet** (generic for Colcrys®)
- PROBENECID tablet
- PROBENECID/COLCHICINE tablet

NONPREFERRED AGENTS
- COLCHICINE capsule (generic for Mitigare®)
- COLCRYS® tablet (colchicine)
- FEBUXOSTAT tablet (generic for Uloric®)
- GLOPERBA® solution (colchicine)
- **MITIGARE® capsule** (colchicine)
- ULORIC® tablet (febuxostat)
- ZYLOPRIM® tablet (allopurinol)

3) ESTROGEN AGENTS

PREFERRED AGENTS
- **CLIMARA PRO® patch** (estradiol/levonorgestrel)
- **ESTRADIOL once weekly transdermal** (generic for Climara®)
- ESTRADIOL oral tablet (generic for Estrace®)
- **ESTRADIOL twice weekly transdermal** (generic for Alora®, Vivelle-Dot®, Minivelle®, Dotti®, Lyllana®)
- **PREMARIN® tablet** (conjugated estrogen)
- **PREMPRO® tablet** (conjugated estrogen/medroxyprogesterone)

NONPREFERRED AGENTS with criteria:
- ANGELIQ® tablet (estradiol/drospirenone)
- ESTRADIOL/NORETHINDRONE ACETATE tablet (generic for Activella®, Mimvey®, Amabelz®, Lopreeza®)
- ETHINYL ESTRADIOL/NORETHINDRONE ACETATE tablet (generic for Jinteli®, Fyavolv®, Femhrt®)
- PREFEST® tablet (estradiol/norgestimate)
- PREMPHASE® tablet (estrogens, conjugated/medroxyprogesterone)

Approval criteria for nonpreferred agents with criteria:

- ≥ 120 days of therapy in the previous 180 days for the same drug, strength, and dosage form

NONPREFERRED AGENTS

- ACTIVELLA® tablet (estradiol/norethindrone acetate)
- ALORA® patch (estradiol)
- AMABELZ® tablet (estradiol/norethindrone acetate)
- BIJUVA® capsule (estradiol/progesterone)
- CLIMARA® patch (estradiol)
- COMBIPATCH® patch (estradiol/norethindrone acetate)
- DIVIGEL® topical gel (estradiol)
- DOTTI® patch (estradiol)
- DUAVEE® tablet (estrogens, conjugated/Bazedoxifene)
- ELESTRIN® gel (estradiol)
- ESTRACE® tablet (estradiol)
- ESTRADIOL vaginal tablet (generic for Vagifem®, Yuvafem®)
- ESTRING® vaginal ring (estradiol)
- EVAMIST® spray (estradiol)
- FEMHRT® tablet (ethinyl estradiol/norethindrone)
- FEMRING® vaginal ring (estradiol acetate)
- FYAVOLV® tablet (ethinyl estradiol/norethindrone)
- JINTELI® tablet (ethinyl estradiol/norethindrone)
- LOPREEZA® tablet (estradiol/norethindrone acetate)
- LYLLANA® patch (estradiol)
- MENEST® tablet (estrogens, esterified)
- MENOSTAR® patch (estradiol)
- MIMVEY® tablet (estradiol/norethindrone acetate)
- MINIVELLE® patch (estradiol)
- VAGIFEM® vaginal tablet (estradiol)
- VIVELLE-DOT® patch (estradiol)
- YUVAFEM® vaginal tablet (estradiol)

4) GI MOTILITY AGENTS (Criteria will be reviewed during the April 2021 DUR Board meeting.)

PREFERRED AGENTS with criteria

- AMITIZA® tablet (lubiprostone)
- **LINZESS® capsule (linaclotide)**
- **MOVANTIK® tablet (naloxegol)**

NONPREFERRED AGENTS

- ALOSETRON tablet (generic for Lotronex®)
- LOTRONEX® tablet (alosetron)
- LUBIPROSTONE tablet (generic for Amitiza®)
- MOTEGRITY® tablet (prucalopride)
- RELISTOR® tablet and injection (methylnaltrexone)
- SYMPROIC® tablet (naldemedine)
- TRULANCE® tablet (plecanatide)
- VIBERZI® tablet (eluxadoline)
- ZELNORM® tablet (tegaserod)

5) HEPATITIS C AGENTS

PREFERRED AGENTS that require manual review for prior authorization

- MAVYRET® tablet (glecaprevir/pibrentasvir)
- RIBAVIRIN capsule and tablet
- **SOFOSBUVIR/VELPATASVIR tablet (generic for Epclusa®)**
- ZEPATIER® tablet (elbasvir/grazoprevir)

NONPREFERRED AGENTS

- **EPCLUSA® tablet (sofosbuvir/velpatasvir)**
- HARVONI® tablet (ledipasvir-sofosbuvir)
- LEDIPASVIR-SOFOSBUVIR tablet (generic for Harvoni®)
- PEGASYS® (peginterferon alpha-2a) pen, vial
- PEGINTRON® (peginterferon alpha-2b) vial kit
- SOVALDI® tablet (sofosbuvir)
- VIEKIRA PAK™ tablet dosepak (ombitasvir-paritaprevir-ritonavir & dasabuvir)
- VOSEVI® tablet (sofosbuvir, velpatasvir, and voxilaprevir)

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

EFFECTIVE IMMEDIATELY:

1. ISOTRETINOIN

INDICATION:

Isotretinoin capsules are indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse effects associated with its use, isotretinoin capsules should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin capsules

DOSING:

The recommended dosage range for isotretinoin capsules is 0.5 to 1 mg/kg/day given in two divided doses with food for 15 to 20 weeks. During treatment, the dose may be adjusted according to response of the disease and/or the appearance of clinical side effects – some of which may be dose related. Adult patients whose disease is very severe with scarring or is primarily manifested on the trunk may require dose adjustments up to 2 mg/kg/day, as tolerated.

If the total nodule count has been reduced by more than 70% prior to completing 15 to 20 weeks of treatment, the drug may be discontinued. After a period of 2 months or more off therapy, and if warranted by persistent or recurring severe nodular acne, a second course of therapy may be initiated. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth. Long-term use of isotretinoin capsules, even in low doses, has not been studied, and is not recommended. It is important that isotretinoin capsules be given at the recommended doses for no longer than the recommended duration.

APPROVAL CRITERIA:

- Recipient must be ≥ 12 years of age; **AND**
- Prescriber must be a dermatologist; **AND**
- Recipient must have a diagnosis of severe recalcitrant nodular acne with many inflammatory nodules measuring a diameter of 5 mm or greater; **AND**
- Recipient has been unresponsive to conventional therapy, including ideally 3 consecutive months using at least 2 of the following (history of each patient will be reviewed on a case-by-case basis):
    - Oral antibiotics (e.g., doxycycline, minocycline)

  - Oral contraceptives (females only)
  - Oral spironolactone (females only)
  - Topical retinoids, topical antibiotics, and/or benzoyl peroxide
  - Combination of oral antibiotics with benzoyl peroxide

****Topical acne medications are not covered by Arkansas Medicaid per Social Security Act 1927.**

Per AAD guidelines:

When prescribing systemic antibiotics, the issue of bacterial resistance remains a major concern. The Centers for Disease Control and Prevention (CDC) has stressed antibiotic stewardship. This is an initiative to promote the appropriate use of antibiotics where patients receive the right dose of the right antibiotic at the right time for the right duration. Limiting antibiotic use to the shortest possible duration, ideally 3-4 months, can be accomplished with the concomitant use of a retinoid or retinoid/BP.

- Prescriber, pharmacy, wholesaler, and recipient must all be registered with the iPLEDGE® Program. Pharmacy claims will not process without all registrations being active; **AND**
- Requests for Absorica 25 mg and 35 mg or Absorica LD require medical necessity over other options; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of severity of acne along with previous therapies including any OTC topical options; **AND**
  - Current labs including CBC, lipid profile, LFTs, and glucose; **AND**
  - Signed copy of iPLEDGE Informed Consent form for both male and female recipients. Female recipients must also sign the Pregnancy Prevention Consent form. If the recipient is under 18, the parent or guardian needs to sign the form in the blank provided. Only the patient is required to initial each item; **AND**
  - Documentation that female recipient of reproductive potential is taking two reliable forms of birth control (one of which must be a primary form—tubal sterilization, male vasectomy, IUD, hormonal contraception) beginning one month before starting isotretinoin and for one month after stopping treatment; **AND**
  - Initial prescription requires documentation of two negative blood or urine pregnancy tests for female recipients of reproductive potential as outlined by iPLEDGE. Documentation of a negative pregnancy test must be provided; **AND**
  - Requested dose (PA is dose specific); **AND**
- Initial PA will be approved for a maximum of 155 days. One (1) renewal is possible only after at least 8 weeks following completion of the first course with a new PA request; **AND**
- Requests for diagnoses other than acne will be reviewed by DHS clinical review team on a case-by-case basis.

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; **OR**
- Prescriber is requesting more than two (2) courses of therapy; **OR**
- Recipient is pregnant; **OR**
- All required information is not provided; **OR**
- Recipient has uncontrolled hypertriglyceridemia (prescriber should submit a treatment plan for patients with high triglycerides).

CONTINUATION CRITERIA:

- Recipient has persistent or recurring severe nodular acne despite the initial 15-20 weeks of therapy; **AND**
- Recipient must have at least 8 weeks between the first and second course of therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs; **AND**
  - Current pregnancy test results.

QUANTITY EDITS:

- #60/30 days for max of 155 days per authorization

EFFECTIVE IMMEDIATELY:

2. GnRH RECEPTOR ANTAGONIST UPDATE (Orilissa® and Oriahnn™)

ORILISSA®
INDICATION:
ORILISSA is indicated for the management of moderate to severe pain associated with endometriosis.

DOSING:
- Exclude pregnancy before starting ORILISSA or start ORILISSA within 7 days from the onset of menses.
- Take ORILISSA at approximately the same time each day, with or without food.
- Use the lowest effective dose, taking into account the severity of symptoms and treatment objectives.
- Limit the duration of use because of bone loss

Table 1. Recommended Dosage and Duration of Use

Dosing Regimen	Maximum Treatment Duration	Coexisting Condition
Initiate treatment with ORILISSA 150 mg once daily	24 months	None
Consider initiating treatment with ORILISSA 200 mg twice daily	6 months	Dyspareunia
Initiate treatment with ORILISSA 150 mg once daily. Use of 200 mg twice daily is not recommended.	6 months	Moderate hepatic impairment (Child-Pugh Class B)

ORIAHNN™
INDICATION:
ORIAHNN is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Limitation of Use:
Use of ORIAHNN should be limited to 24 months due to the risk of continued bone loss, which may not be reversible

DOSING:
- Exclude pregnancy before starting ORIAHNN or start ORIAHNN within 7 days from the onset of menses.
- The recommended dosage of ORIAHNN is:
  - One elagolix 300 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg capsule in the morning (AM), and
  - One elagolix 300 mg capsule in the evening (PM).
- Take the morning and evening capsules at approximately the same time each day, with or without food.
- The recommended duration of treatment with ORIAHNN is 24 months

APPROVAL CRITERIA for both ORILISSA and ORIAHNN unless specified:
- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of moderate to severe pain associated with endometriosis for ORILISSA requests **OR** a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas/fibroids for ORIAHNN requests **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be premenopausal; **AND**

- Attestation that recipient of reproductive potential will use effective non-hormonal contraception during treatment and for 1 week after discontinuing therapy; **AND**
- Recent dual-energy X-ray absorptiometry (DXA) scan results for documentation of baseline bone mineral density for patients at high risk of osteoporosis. Examples of high-risk patients include but are not limited to the following:
    - History of low-trauma fracture
    - Taking other medications that may decrease BMD (i.e., corticosteroids, anticonvulsants, PPIs)
    - Parent or sibling with osteoporosis
- Documentation of negative pregnancy status by one of the following:
    - Current negative pregnancy test results in patient with reproductive potential; **OR**
    - Documentation of beginning medication within 7 days of onset of menses; **OR**
    - Documentation of tubal ligation

- **Provider must submit the following for ORILISSA requests:**
    - Current chart notes documenting symptom history, all previous treatments for endometriosis, and that the pelvic pain is not due to other causes; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Confirmation of endometriosis by pelvic exam results **AND** at least one of the following:
        - Transvaginal ultrasound; **OR**
        - Magnetic Resonance Imaging; **OR**
        - Laparoscopy or laparotomy; **OR**
        - Biopsy report confirming diagnosis.
    - Documentation that recipient has tried and failed **at least 2** medications in the following drug classes with at least a **3-month history** of each:
        - NSAID and/or acetaminophen usage
        - Contraceptives (Combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, and vaginal rings)
        - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
        - Intrauterine device
    - Letter outlining the medical necessity of ORILISSA over other treatment options (i.e., OTC pain medications, hormonal contraception, progestin therapy, and surgery); **AND**
    - Recipient must use the lowest effective dose possible but may titrate taking into account severity of symptoms. Documentation of initial starting dose from one of the following:
        - 150 mg once daily for 24 months--Recipient has no hepatic impairment or dyspareunia
        - 200 mg twice daily for 6 months—Recipient has dyspareunia
        - 150 mg once daily for 6 months—Recipient has moderate hepatic impairment (Child-Pugh B)

- **Provider must submit the following for ORIAHNN requests:**
    - Current chart notes documenting symptom history and all previous treatments for uterine leiomyomas/fibroids with heavy menstrual bleeding/painful menstrual cycles; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Confirmation of uterine fibroids by pelvic exam results **AND** at least one of the following:
        - Transabdominal or transvaginal ultrasound; **OR**
        - Magnetic Resonance Imaging; **OR**
        - Computerized Tomography scan; **OR**
        - Hysterosalpingogram or sonohysterogram; **OR**
        - Laparoscopy or hysteroscopy
    - Letter outlining the medical necessity of ORIAHNN over other treatment options (i.e., OTC pain medications, hormonal contraception, IUD, and surgery); **AND**
    - Documentation that recipient has tried and failed **at least 2** medications in the following drug classes with at least a **3-month history** of each:
        - NSAID and/or acetaminophen usage
        - Contraceptives (Combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, or vaginal rings)
        - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
        - Intrauterine device
        - Tranexamic acid

DENIAL CRITERIA for both ORILISSA and ORIAHNN unless specified:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is postmenopausal; **OR**
- Recipient has a diagnosis of osteoporosis or osteopenia (T-score < -1.0 SD); **OR**
- Recipient has history of major depression or PTSD in last 2 years **OR** history of major psychiatric disorder (i.e., schizophrenia or bipolar) **OR** history of suicide attempt in the last year; **OR**
- Recipient is pregnant; **OR**
- Recipient has severe hepatic impairment (Child-Pugh C), and dose modifications may be needed for moderate hepatic impairment; **OR**
- Recipient requires concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil); **OR**
- Prescriber requests for > 24 months of treatment for ORIAHNN and ORILISSA patients with no coexisting conditions; requests for > 6 months of treatment for ORILISSA patients with either dyspareunia or moderate hepatic impairment; **OR**
- ORILISSA recipient has chronic pelvic pain that is not caused by endometriosis (e.g., pelvic inflammatory disease, inflammatory bowel disease, ovarian cysts); **OR**
- ORIAHNN recipient with any of the following:
    - Over 35 years of age **and** currently smokes; **OR**
    - History of breast cancer or other hormonally-sensitive malignancies; **OR**
    - History of or high risk for arterial, venous thrombotic or thromboembolic disorder; **OR**
        - Deep vein thrombosis or pulmonary embolism; **OR**
        - Vascular disease; **OR**
        - Thrombogenic valvular or thrombogenic rhythm disease of the heart; **OR**
        - Inherited or acquired hypercoagulopathies; **OR**
        - Uncontrolled hypertension; **OR**
        - Headaches with focal neurological symptoms or have migraine headaches with aura (over 35 years of age); **OR**
    - History of heavy bleeding associated with uterine fibroids that has not caused anemia (hemoglobin level ≤ 12 g/dL); **OR**
    - Undiagnosed abnormal uterine bleeding.

CONTINUATION CRITERIA:

- Recipient has been compliant on medication; **AND**
- Recipient has noted improvement of symptoms with noted reduction in endometriosis-associated pain in ORILISSA patients and decrease in heavy menstrual bleeding with improvement of hemoglobin level in ORIAHNN patients; **AND**
- Recipient remains free from hepatic impairment, osteoporosis, psychiatric disorders, and pregnancy; **AND**
- Recipient has not surpassed the maximum treatment durations; **AND**
    - ORIAHNN—has not exceeded 24 months total
    - ORILISSA—has not exceeded 24 months total for no coexisting condition **OR** has not exceeded 6 months in dyspareunia patients and those with moderate hepatic impairment
- Prescriber must submit the following:
    - Current chart notes with documentation of positive response to therapy; **AND**
    - Current labs including CBC and LFTs; **AND**
    - Documentation of negative pregnancy status; **AND**
- Attestation that recipient of reproductive potential will continue to use effective non-hormonal contraception during treatment.

QUANTITY EDITS:

ORILISSA

- **150 mg**--#28/28 days (max of 24 months)
- **200 mg**--#56/28 days (max of 6 months)

ORIAHNN 300-1-0.5 mg/ 300 mg

- #56/28 (max of 24 months)

EFFECTIVE IMMEDIATELY:

3. THROMBOPOIESIS STIMULATING PROTEINS (Promacta®, Mulpleta®, Doptelet®, and Tavalisse™)

INDICATION:

PROMACTA

- Indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. PROMACTA should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. PROMACTA should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
- Indicated in combination with standard immunosuppressive therapy (IST) for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia and patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

MULPLETA

- Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

DOPTELET

- Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
- Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

TAVALISSE

- Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

DOSING:

PROMACTA

- **ITP**--Use the lowest dose of PROMACTA to achieve and maintain a platelet count greater than or equal to 50 x 10^9/L as necessary to reduce the risk for bleeding. Dose adjustments are based upon the platelet count response. Do not use PROMACTA to normalize platelet counts.
- **Hep C Thrombocytopenia**--Use the lowest dose of PROMACTA to achieve and maintain a platelet count necessary to initiate and maintain antiviral therapy with pegylated interferon and ribavirin. Dose adjustments are based upon the platelet count response. Do not use PROMACTA to normalize platelet counts
- **Aplastic Anemia**—Initiate concurrently with standard immunosuppressive therapy; recommendations vary depending on age and race.

MULPLETA

Begin MULPLETA dosing 8-14 days prior to a scheduled procedure. Patients should undergo their procedure 2-8 days after the last dose. The recommended dosage of MULPLETA is 3 mg taken orally once daily with or without food for 7 days. MULPLETA should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.

DOPTELET

- **Chronic liver disease**--Begin DOPTELET dosing 10 to 13 days prior to the scheduled procedure. The recommended daily dose of DOPTELET is based on the patient's platelet count prior to the scheduled procedure and should be taken once daily for 5 consecutive days. Patients should undergo their procedure 5 to 8 days after the last dose of DOPTELET.
- **ITP**--Use the lowest dose of DOPTELET needed to achieve and maintain a platelet count greater than or equal to 50 x10^9/L as necessary to reduce the risk for bleeding. Dose adjustments are based on platelet count response. Do not use DOPTELET to normalize platelet counts. DOPTELET should be discontinued if platelets are < 50 × 10^9/L after 4 weeks at 40mg OR platelets > 400 × 10^9/L after 2 weeks of 20mg. Initial Dose Regimen: Begin DOPTELET at a starting dose of 20 mg (1 tablet) once daily with food.

TAVALISSE

- Initiate TAVALISSE at a dose of 100 mg taken orally twice daily. After a month, if platelet count has not increased to at least 50 × 10^9/L, increase TAVALISSE dose to 150 mg twice daily.

Use the lowest dose of TAVALISSE to achieve and maintain a platelet count at least 50×10^9/L as necessary to reduce the risk of bleeding. Manufacturer's package insert outlines many dose modification scenarios.

MULPLETA APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has thrombocytopenia with baseline platelet count of < 50,000/µL **AND** a diagnosis of chronic liver disease **AND** is scheduled to undergo a procedure **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be scheduled for a procedure that would require a platelet transfusion to address risk of bleeding (i.e., liver ablation/coagulation, transcatheter arterial chemoembolization, liver biopsy, gastrointestinal endoscopy, dental extraction, diagnostic paracentesis or laparocentesis, septoplasty, embolization of splenic artery aneurysm, bone marrow biopsy, removal of cervical polyp or inguinal hernia repair); **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of upcoming procedure and history of liver disease; **AND**
    - Prescriber must submit documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
    - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
    - Type of procedure; **AND**
    - Date of procedure (Dosing must begin 8-14 days prior to procedure, and dosing should end 2-8 days prior to procedure); **AND**
    - Document if a platelet transfusion will be given prior to surgery; **AND**
    - If used previously, provide chart notes and labs with documentation of response.

MULPLETA DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Recipient was a non-responder to previous therapy of either Doptelet or Mulpleta (Defined as not reaching a platelet count of at least 50,000/µL **AND** platelet count did not increase by at least 20,000/µL from baseline); **OR**
- Prescriber requesting more than a 7 days' supply; **OR**
- Prescriber is attempting to normalize platelet counts; **OR**
- Recipient has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Prescriber determines recipient will need a platelet transfusion for procedure prior to beginning therapy; **OR**
- Recipient is prescribed concomitant thrombopoietic agents or spleen tyrosine kinase inhibitor (i.e., eltrombopag, romiplostim, fotamatinib); **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient's procedure includes laparotomy, thoracotomy, open-heart surgery, craniotomy, or organ resection; **OR**
- Recipient has Child-Pugh C liver disease or uncontrolled hepatic encephalopathy.

CONTINUATION CRITERIA:

- No continuation as this is a 7-day course of therapy

DOPTELET APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of either thrombocytopenia due to chronic liver disease and scheduled for a procedure **OR** chronic immune thrombocytopenia with insufficient response to a previous treatment **OR** a diagnosis consistent with FDA indications; **AND**

Chronic Liver Disease

- Recipient with chronic liver disease requires dosing based on platelet count prior to procedure; **AND**
    - Platelet count < 40,000/µL—dose is 60mg once daily for 5 days
    - Platelet count ≥ 40,000/µL to < 50,000/µL—dose is 40mg once daily for 5 days
- Recipient must be scheduled for a procedure that would require a platelet transfusion to address risk of bleeding without this medication (i.e., liver ablation/coagulation, transcatheter arterial

chemoembolization, liver biopsy, gastrointestinal endoscopy, dental extraction, diagnostic paracentesis or laparocentesis, septoplasty, embolization of splenic artery aneurysm, bone marrow biopsy, removal of cervical polyp or inguinal hernia repair); **AND**

- Prescriber must submit the following:
  - Current chart notes with documentation of upcoming procedure and history of liver disease; **AND**
  - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
  - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
  - Type of procedure; **AND**
  - Date of procedure (Dosing must begin 10-13 days prior to procedure and end 5-8 days prior to procedure); **AND**
  - Document if a platelet transfusion will be given prior to surgery; **AND**
  - If used previously, provide chart notes and labs with documentation of response.

Chronic Immune Thrombocytopenia

- Recipient with chronic immune thrombocytopenia has a baseline platelet count of < 50,000/µL; **AND**
  - Initiate dose at 20 mg once daily
  - Titrate dose to keep platelets ≥ 50,000/µL with a max dose of 40 mg once daily
- Recipients requiring concomitant moderate or strong dual inhibitors of CYP2C9 and CYP3A4 must start dose at 20 mg three times per week; **AND**
- Recipient requiring concomitant moderate or strong dual inducers of CYP2C9 and CYP3A4 must start dose at 40 mg once daily; **AND**
- Recipient has documented failure of two (2) or more prior chronic immune thrombocytopenia therapies (including, but not limited to corticosteroids, immunoglobulins, azathioprine, danazol, cyclophosphamide and/or rituximab) **AND** failure with eltrombopag; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies tried; **AND**
  - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion, and Promacta (eltrombopag)); **AND**
  - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
  - If used previously, provide chart notes and labs with documentation of response; **AND**
  - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
- Initial PA for one month only.

DOPTELET DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Prescriber is attempting to normalize platelet counts; **OR**
- Recipient has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Recipient is prescribed concomitant thrombopoietic agents or spleen tyrosine kinase inhibitor (i.e., eltrombopag, romiplostim, fotamatinib); **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient has a history of hepatocellular carcinoma, cirrhosis, portal hypertension, chronic active hepatitis, or uncontrolled hepatic encephalopathy; **OR**
- Recipient has a baseline platelet count of ≥ 50,000/µL.

Chronic Liver Disease

- Prescriber requesting more than a 5 days' supply; **OR**
- Recipient was a non-responder to previous therapy of either DOPTELET or MULPLETA (Defined as requiring a platelet transfusion or any rescue procedure for bleeding up to 7 days following the elective procedure); **OR**
- Prescriber determines recipient will need a platelet transfusion for procedure prior to beginning therapy; **OR**
- Recipient's procedure includes neurosurgical interventions, thoracotomy, laparotomy, or organ resection

Chronic Immune Thrombocytopenia

- Recipient has platelet count <50,000/µL after 4 weeks at 40 mg once daily; **OR**

- Recipient has platelet count >400,000/µL after 2 weeks at 20 mg once weekly; **OR**
- Recipient has a history of myelodysplastic syndrome; **OR**
- Recipient has not received one or more prior chronic immune thrombocytopenia therapies (including, but not limited to corticosteroids, immunoglobulins, azathioprine, danazol, cyclophosphamide and/or rituximab) **AND** eltrombopag.

CONTINUATION CRITERIA:

- No continuation for CLD recipient as this is a 5-day course of therapy. See below for ITP requirements.

TAVALISSE APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of chronic immune thrombocytopenia and has had an insufficient response to a previous treatment **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient has a baseline platelet count of < 50,000/µL; **AND**
- Recipient has documented failure of two (2) or more prior chronic immune thrombocytopenia therapies (including, but not limited to corticosteroids, immunoglobulins, azathioprine, danazol, cyclophosphamide and/or rituximab) **AND** failure with eltrombopag; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous treatments; **AND**
    - Current labs including CBC and LFTs (must be within a week of PA request); **AND**
    - Current vital signs including blood pressure; **AND**
    - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion, and Promacta® (eltrombopag)); **AND**
    - If used previously, provide chart notes and labs with documentation of response; **AND**
    - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
- Initial PA for one month only for first 3 months.

TAVALISSE DENIAL CRITERIA

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Recipient cannot tolerate the minimum dose of 100 mg once daily; **OR**
- Prescriber is attempting to normalize platelet counts; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient is in hypertensive crisis with blood pressure > 180/120 mmHg or >160/100 mmHg after 4 weeks of aggressive hypertensive treatment; **OR**
- Recipient has signs of hepatotoxicity with AST/ALT 3X ULN AND Total Bili > 2X ULN; **OR**
- Discontinue if platelet counts do not increase to a level sufficient to avoid clinically important bleeding after 12 weeks.

CONTINUATION CRITERIA:

- See below for requirements

PROMACTA APPROVAL CRITERIA:

- Recipient must have a diagnosis of thrombocytopenia with chronic immune thrombocytopenia with insufficient response to corticosteroids, immunoglobulin, or splenectomy, **OR** chronic hepatitis C in which thrombocytopenia prevents the initiation of interferon-based therapies, **OR** severe aplastic anemia in combination with standard immunosuppressive therapy as first-line therapy, **OR** severe aplastic anemia with insufficient response to immunosuppressive therapy, **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient has a baseline platelet count of < 50,000/µL; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapies tried with response; **AND**
    - Current labs:
        - LFTs prior to therapy initiation, every 2 weeks during dose adjustment, then monthly once dosing is stable (If abnormal, monitor weekly); **AND**
        - CBC with differential (including platelets) prior to therapy, every week until platelet count is stable, then monthly; **AND**

  - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
  - If used previously, provide chart notes and labs with documentation of response; **AND**
  - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
  - Verify required dose—dose reductions may be needed for patients with mild, moderate, or severe hepatic impairment and patients with Asian ancestry (such as Chinese, Japanese, Taiwanese, Korean, or Thai) with ITP or severe aplastic anemia; **AND**
- Initial PA for one month only.

Chronic Immune Thrombocytopenia
- Recipient must be ≥ 1 year of age; **AND**
- Dose requirements
  - 1-5 years of age begin with 25 mg once daily
  - ≥ 6 years of age begin with 50 mg once daily
  - Max of 75 mg daily
  - Asian ancestry **OR** hepatic impairment, begin with 25 mg once daily
  - Asian ancestry **AND** hepatic impairment, begin with 12.5 mg once daily

Interferon treatment for Hepatitis C patients
- Recipient must be ≥ 18 years of age; **AND**
- Dose requirements; **AND**
  - Begin with 25 mg once daily
  - Max of 100 mg once daily
- Recipient must be prescribed interferon-based therapies.

Severe Aplastic Anemia
- Recipient must be ≥ 2 years of age; **AND**
- Dose requirements; **AND**
  - First-line with immunosuppressive therapy—
    - 2-5 years of age begin with 2.5 mg/kg
    - 6-11 years of age begin with 75 mg daily
    - ≥ 12 years of age begin with 150 mg daily
    - Do not exceed the initial dose (above are beginning and max doses per age)
  - Refractory—
    - Begin with 50 mg once daily
    - Titrate based on platelet count
    - Max of 150 mg once daily
    - If no hematologic response after 16 weeks, discontinue PROMACTA
  - Asian ancestry or hepatic impairment—
    - ≥ 12 years of age begin with 75 mg daily
    - 6-11 years of age begin with 37.5 mg daily
    - 2-5 years of age begin with 1.25 mg/kg daily
    - Refractory begin with 25 mg once daily
- Treatment duration is maximum of 6 months.

PROMACTA DENIAL CRITERIA:
- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has a diagnosis of myelodysplastic syndrome; **OR**
- Hepatitis C recipient is not being treated for HCV infection or the recipient has been prescribed a direct-acting antiviral agent instead of interferon; **OR**
- Recipient platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Recipient has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Platelet count is >400,000/µL after 2 weeks at lowest PROMACTA dose; **OR**
- Aplastic anemia recipient is not prescribed standard immunosuppressive therapy along with PROMACTA for first-line treatment; **OR**
- Prescriber has requested a dose >150 mg daily for aplastic anemia, or >75 mg daily for ITP, or >100 mg daily for interferon treatment of hepatitis C; **OR**
- Prescriber requests PROMACTA for longer than 6 months in aplastic anemia.

CONTINUATION CRITERIA for all medications:

- Recipient is compliant on therapy; AND
- Recipient maintains a platelet count of ≥50,000/µL on doses within manufacturer's recommendation; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including CBC and LFTs and labs since last PA review (See approval criteria for lab frequency); AND
  - Documentation of response to therapy (Provide information on required corticosteroids, IVIG, or platelet transfusion during treatment, etc.); AND
  - Dose requested based on abnormal platelet counts; AND
- Hepatitis C recipient remains on Interferon therapy for PROMACTA request.

QUANTITY EDITS (quantities outside of edits below will be reviewed on a case-by-case basis):

TAVALISSE
#62/31 days
PROMACTA
50 mg--#62/31 days; all other strengths--#31/31 days
MULPLETA
#7 per claim/PA
DOPTELET
#15 per claim/PA for platelet <40,000/µL (NDC 71369-0020-15)
#10 per claim/PA for platelet 40,000-50,000/µL (NDC 71369-0020-10)
#62/31 days (NDC 71369-0020-30)

EFFECTIVE IMMEDIATELY:

4. IMMUNOMODULATORS FOR ASTHMA (Fasenra®, Dupixent®, Xolair® and Nucala®)

INDICATIONS:

FASENRA

- Indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

DUPIXENT

- Indicated for the treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.
- Indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- Indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

XOLAIR

- Indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
- Indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.
- Indicated for add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

NUCALA

- Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
- Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Indicated for the treatment of adult and pediatric patients aged 12 years and older with hyper-eosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause

DOSING FOR ASTHMA:

FASENRA

The recommended dose of FASENRA is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

DUPIXENT

The recommended dose of DUPIXENT for adults and adolescents (12 years of age and older) is:

- an initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week or
- an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week
- for patients with oral corticosteroids-dependent asthma, or with co-morbid moderate-to-severe atopic dermatitis for which DUPIXENT is indicated, start with an initial dose of 600 mg followed by 300 mg given every other week

XOLAIR

Administer XOLAIR 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL) measured before the start of treatment, and by body weight (kg).

NUCALA

The recommended dosage of NUCALA in adults and adolescents aged 12 years and older is 100 mg administered once every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen. The recommended dosage of NUCALA for injection in children aged 6 to 11 years is 40 mg administered once every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen.

APPROVAL CRITERIA (Asthma diagnosis only--Criteria for other indications remain the same as previously discussed. PA requests for new indications will be reviewed manually on a case-by-case basis.):

- Recipient must be at least the minimum age (allowed age will be updated if FDA indication changes); **AND**
  - NUCALA—≥ 6 years of age
  - FASENRA--≥ 12 years of age
  - DUPIXENT--≥ 12 years of age
  - XOLAIR—≥ 6 years of age
- Recipient must have a diagnosis consistent with FDA indications (current indication below); **AND**
  - NUCALA—add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype
  - FASENRA—add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype
  - DUPIXENT—add-on maintenance treatment in patients with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
  - XOLAIR—moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- Recipient must be 100% compliant on at least two asthma maintenance medications for the last 12 months (one must be an inhaled corticosteroid at a maximized dose); **AND**
- Recipient has no therapeutic duplication with any interleukins; **AND**
- Prescriber must be a board-certified Allergy and Immunology specialist; **AND**
- Recipient has 2 or more exacerbations despite compliance on ICS plus an additional controller medication in the last 12 months. Exacerbation is defined as requiring systemic corticosteroids, an emergency department visit, or hospitalization for asthma; **AND**
- Recipient ≥ 18 years of age must have a pre-bronchodilator FEV1 < 80%; Recipient < 18 years of age must have a pre-bronchodilator FEV1 < 90%; **AND**
- Recipient must meet manufacturer's recommendations at baseline for one (1) of the following:
  - Serum IgE (XOLAIR); **OR**
  - Blood eosinophil count (DUPIXENT, NUCALA, AND FASENRA); **OR**
  - Dependent upon oral corticosteroids if not eosinophilic type (DUPIXENT); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapies tried for asthma with response; **AND**
  - Baseline blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), AND NUCALA; Baseline serum IgE levels, body weight, and completed form for XOLAIR; **AND**
  - Baseline Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only; **AND**

- Current Pulmonary Function Test results; **AND**
- Letter of medical necessity for requested product over the preferred medication (currently FASENRA) and other therapies outlined in treatment guidelines.

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has not been compliant with two asthma maintenance medications for at least 12 months including an inhaled corticosteroid (ICS or ICS/LABA); **OR**
- Recipient has approval for another asthma immunomodulator; **OR**
- Recipient has a baseline blood eosinophil level or baseline serum IgE level that falls outside of manufacturer's requirements; **OR**
- Recipient is a current smoker; **OR**
- Recipient has helminth infections. Pre-existing helminth infections should be treated prior to beginning therapy; **OR**
- If approved, recipient must remain compliant on asthma controller medications including inhaled corticosteroids and immunomodulator.

CONTINUATION CRITERIA:

- Recipient is compliant on asthma controller medication (ICS or ICS/LABA) and immunomodulator injection; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy after 12 months of treatment; **AND**
  - Current PFTs; **AND**
  - Current blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), and NUCALA; **AND**
  - Current serum IgE level and body weight for XOLAIR; **AND**
  - Current Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only; **AND**
- Recipient must have an improvement in FEV1 over baseline; **AND**
- Recipient must have fewer exacerbations; **AND**
- Recipient must have a decrease in blood eosinophil count **OR** serum IgE **OR** decrease in corticosteroid usage.

QUANTITY EDITS:

FASENRA--#1 pen/vial per 8 weeks (will need quantity override for first 3 months)
DUPIXENT--#5 syringes per 50 days
NUCALA--#3 prefilled syringes/autoinjectors per 28 days (based on other indications)
XOLAIR--#8 150 mg prefilled syringe/vial per 28 days; #1 75 mg prefilled syringe per 28 days

EFFECTIVE IMMEDIATELY:

5. XPOVIO® (selinexor)

INDICATIONS:

Multiple Myeloma

- XPOVIO in combination with dexamethasone is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma 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.
- XPOVIO in combination with bortezomib and dexamethasone is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **(NEW INDICATION SINCE LAST REVIEW)**

Diffuse Large B-Cell Lymphoma (NEW INDICATION SINCE LAST REVIEW)
XPOVIO is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

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(s).

DOSING:

Recommended Dosage for Multiple Myeloma

- **In combination with Dexamethasone:**

The recommended dosage of XPOVIO is 80 mg taken orally on Days 1 and 3 of each week until disease progression or unacceptable toxicity. Administer dexamethasone 20 mg orally with each dose of XPOVIO on Days 1 and 3 of each week. For additional information regarding the administration of dexamethasone, refer to its prescribing information.

- **In combination with Bortezomib and Dexamethasone:**

The recommended dosage of XPOVIO is 100 mg taken orally once weekly on Day 1 of each week until disease progression or unacceptable toxicity in combination with:

  - Bortezomib 1.3 mg/m^2 administered subcutaneously once weekly on Day 1 of each week for 4 weeks followed by 1 week off.
  - Dexamethasone 20 mg taken orally twice weekly on Days 1 and 2 of each week.

Recommended Dosage for Diffuse Large B-Cell Lymphoma

The recommended dosage of XPOVIO is 60 mg taken orally on Days 1 and 3 of each week until disease progression or unacceptable toxicity.

Table 1: XPOVIO Dosage Reduction Steps for Adverse Reactions

	Multiple Myeloma In Combination with Bortezomib and Dexamethasone (SVd)	Multiple Myeloma In Combination with Dexamethasone (Sd)	Diffuse Large B-Cell Lymphoma
Recommended Starting Dosage	100 mg once weekly	80 mg Days 1 and 3 of each week (160 mg total per week)	60 mg Days 1 and 3 of each week (120 mg total per week)
First Reduction	80 mg once weekly	100 mg once weekly	40 mg Days 1 and 3 of each week (80 mg total per week)
Second Reduction	60 mg once weekly	80 mg once weekly	60 mg once weekly
Third Reduction	40 mg once weekly	60 mg once weekly	40 mg once weekly
Fourth Reduction	Permanently discontinue	Permanently discontinue	Permanently discontinue

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of multiple myeloma **OR** diffuse large B-cell lymphoma **OR** a diagnosis consistent with FDA indications; AND
- Recipient with multiple myeloma requires one of the following:
  - Recipient must have at least one prior therapy and will take XPOVIO in combination with bortezomib and dexamethasone; **OR**
  - Recipient with relapsed or refractory disease has received at least four prior therapies and disease is refractory to at least two 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 will take XPOVIO in combination with dexamethasone
- Recipient with relapsed or refractory diffuse large B-cell lymphoma requires a failure of at least 2 lines of systemic therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of diagnosis and previous therapies; **AND**
  - Current labs including CBC with differential, complete metabolic panel, and LFTs; **AND**
  - Required dosage since dose adjustments are required for thrombocytopenia, neutropenia, anemia, extreme nausea/vomiting, diarrhea, hyponatremia, and ocular toxicity (refer to manufacturer's package insert); **AND**
  - Verification that recipient has been prescribed concomitant 5-HT3 receptor antagonists or other anti-nausea agents; **AND**
  - Treatment plan for potential nausea and dehydration; **AND**
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipients with DLBCL that had an autologous hematopoietic stem cell transplantation; **OR**
- Recipient cannot tolerate the following minimum dosages; **OR**
  - 40 mg weekly for multiple myeloma in combination with bortezomib and dexamethasone
  - 60 mg weekly for multiple myeloma in combination with dexamethasone
  - 40 mg weekly for diffuse large B-cell lymphoma
- Recipient is pregnant or breastfeeding; **OR**
- Multiple myeloma recipients are not prescribed the required concomitant therapy based on FDA indications; **OR**
- Recipient has active smoldering multiple myeloma; **OR**
- Recipient has active plasma cell leukemia; **OR**
- Recipient has documented systemic amyloid light chain amyloidosis; **OR**
- Recipient has active CNS multiple myeloma; **OR**
- Recipient with DLBCL has not failed at least two prior therapies; **OR**
- Recipient with relapsed or refractory multiple myeloma has not failed at least four prior therapies.

CONTINUATION CRITERIA:

- Recipient has no disease progression or unacceptable toxicity; **AND**
- Recipient with multiple myeloma continues to take bortezomib **and/or** dexamethasone; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy; **AND**
  - Current labs including CBC with differential and complete metabolic panel (especially need neutrophil count, platelets, hemoglobin, and sodium); **AND**
  - Current weight; **AND**
  - Current required dose; **AND**
- Once stable, PA's may be approved 3 months at a time.

QUANTITY EDITS:

- #32/ 28 days

EFFECTIVE IMMEDIATELY:

6. GAVRETO™ (pralsetinib)

INDICATIONS:

- Adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test;
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy;
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-fusion positive thyroid cancer (TC) who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

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

DOSING:

The recommended dosage of GAVRETO is 400 mg orally once daily on an empty stomach (no food intake for at least 2 hours before and at least 1 hour after taking GAVRETO). Continue treatment until disease progression or until unacceptable toxicity.

Table 1: Recommended Dose Reductions for GAVRETO for Adverse Reactions

Dose Reduction	Recommended Dosage
First	300 mg once daily
Second	200 mg once daily
Third	100 mg once daily

Permanently discontinue GAVRETO in patients who are unable to tolerate 100 mg taken orally once daily.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age if diagnosed with NSCLC and ≥ 12 years of age for thyroid cancer; **AND**
- Recipient must be diagnosed with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC), advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, or advanced/metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have non-resectable disease; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of diagnosis with lab work confirming the presence of a RET gene fusion or gene mutation; **AND**
    - Current labs including CBC with differential, complete metabolic panel, calcitonin levels for medullary thyroid cancer; **AND**
    - Current blood pressure (hypertension must be controlled); **AND**
    - Documentation of previous therapies including radioactive iodine in RET fusion-positive thyroid cancer; **AND**
        - NSCLC—may be used first-line, but many patients start on platinum therapy
        - MTC—may have used cabozantinib, vandetanib, or naïve to both agents
        - TC—failure of standard therapy with radioactive iodine and sorafenib and/or lenvatinib
    - Attestation that recipients of reproductive potential are not pregnant and counseled to use effective non-hormonal contraception; **AND**
- Initial approval will be three (3) months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has no documentation of RET gene fusion or RET gene mutation; **OR**
- Recipient cannot tolerate the minimum dose of 100 mg once daily; **OR**
- Recipient has recurrent interstitial lung disease/pneumonitis (grade 1 or 2) **OR** grade 3 or 4 reaction; **OR**
- Recipient has uncontrolled hypertension (180/100 mmHg)—HTN therapy may be required; **OR**
- Recipient has a history of severe or life-threatening hemorrhage; **OR**
- Recipient has moderate or severe hepatoxicity (may require dose decrease initially); **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient requires concomitant strong CYP3A inhibitor or combined P-gp and strong CYP3A inhibitor (e.g., clarithromycin, ketoconazole, ritonavir); **OR**
- Recipient baseline labs
    - Platelets < 75 X 10^9/L
    - ANC < 1.0 X 10^9/L
    - Hb < 9 g/dL
    - CrCl < 40 ml/min
    - Total serum phosphorus > 5.5 mg/dL

CONTINUATION CRITERIA:

- Recipient has no evidence of disease progression or unacceptable toxicity; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including CBC with differential and complete metabolic panel (LFTs should be monitored every 2 weeks during the first 3 months) and calcitonin level (will increase with medullary thyroid cancer recurrence); **AND**
    - Current blood pressure; **AND**
    - Attestation that recipient with reproductive potential is not pregnant and continues to use effective non-hormonal contraception.

QUANTITY EDITS:

- #120/30 days

EFFECTIVE IMMEDIATELY:

7. ONGENTYS™ (opicapone)

INDICATION:

ONGENTYS is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

DOSING:

- The recommended dosage of ONGENTYS is 50 mg administered orally once daily at bedtime. Patients should not eat food for 1 hour before and for at least 1 hour after intake of ONGENTYS.
- In patients with moderate hepatic impairment (Child-Pugh B), the recommended dose of ONGENTYS is 25 mg orally once daily at bedtime. Avoid use of ONGENTYS in patients with severe (Child-Pugh C) hepatic impairment.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of Parkinson's Disease for at least 3 years and experiencing "off" episodes while compliant on levodopa/carbidopa OR a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including LFTs and renal function; AND
- Recipient should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; AND
- Recipient must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting ONGENTYS; AND
- Recipient must be taking at least 3 doses of levodopa per day; AND
- Recipient must take ONGENTYS in combination with levodopa/carbidopa; AND
- Recipient must be experiencing at least 2 hours of OFF time per day excluding in the morning prior to first dose of the day; AND
- If taking other PD medications along with levodopa/carbidopa, recipient must be on a stable dose for at least 4 weeks prior to starting ONGENTYS (e.g., COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine); AND
- Prescriber must provide the medical necessity over the increase in levodopa/carbidopa dose, changing to extended-release formulations, and changing to Stalevo/entacapone + levodopa/carbidopa.

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is diagnosed with severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is diagnosed with end stage renal disease; **OR**
- Recipient has a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; **OR**
- Recipient takes concomitant non-selective monoamine oxidase (MAO) inhibitors; **OR**
- Recipient is diagnosed with a major psychotic disorder in the last year (i.e., major depressive disorder, bipolar, psychosis, generalized anxiety disorder); **OR**
- Recipient has < 2 hours a day of OFF time; **OR**
- Recipient has a diagnosis of atypical parkinsonism or secondary parkinsonism variants; **OR**
- Recipient is pregnant or breastfeeding.

CONTINUATION CRITERIA:

- Prescriber must submit the following:
  - Current chart notes indicating the patient has responded to therapy indicated by the reduction in "off" episodes and an increase in "on" episodes compared to baseline; **AND**
  - Chart notes monitoring for the absence of adverse effects during treatment including new or worsening dyskinesia, development of impulse control disorders, hallucinations, and other symptoms of psychosis; **AND**
- Recipient must continue and be compliant with levodopa/carbidopa as well as ONGENTYS.

QUANTITY EDITS:

- #30/30

EFFECTIVE IMMEDIATELY:

8. **ONUREG® (azacitidine)**

INDICATION:

ONUREG is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

Do not substitute ONUREG for intravenous or subcutaneous azacitidine. The indications and dosing regimen for ONUREG differ from that of intravenous or subcutaneous azacytidine.

DOSING:

The recommended dosage of ONUREG is 300 mg orally once daily with or without food on Days 1 through 14 of each 28-day cycle. Continue ONUREG until disease progression or unacceptable toxicity.

Administer an antiemetic 30 minutes prior to each dose of ONUREG for the first 2 cycles. Antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting.

If the absolute neutrophil count (ANC) is less than 0.5 Gi/L on Day 1 of a cycle, do not administer ONUREG. Delay the start of the cycle until the ANC is 0.5 Gi/L or more.

APPROVAL CRITERIA:

- Recipient must be ≥ 55 years of age; AND
- Recipient must have the diagnosis of acute myeloid leukemia and either achieved first complete remission OR complete remission with incomplete blood count recovery after intensive induction chemotherapy and are not able to compete intension curative therapy OR a diagnosis consistent with FDA indication; AND
- Recipient should not be substituting ONUREG for IV or subcutaneous azacitidine at the same doses; AND
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies and response; AND
  - Current labs including CBC with differential and LFTs (delay therapy cycle if ANC <0.5 Gi/L); AND
  - Required dosage since dose adjustments are required for neutropenia, thrombocytopenia, and gastrointestinal toxicity; AND
- Recipient must not be a candidate for hematopoietic stem cell transplant; AND
- Recipient must be prescribed an antiemetic for use during the first 2 cycles; AND
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has not received recent intensive induction chemotherapy; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient cannot tolerate the minimum dose of 200 mg per day with a reduced treatment duration of 7 days; OR
- Recipient has a diagnosis of myelodysplastic syndrome; OR
- Recipient has moderate to severe hepatic impairment (total bilirubin >1.5 to 3 X ULN); OR
- Recipient had a prior bone marrow or stem cell transplantation.

CONTINUATION CRITERIA:

- Recipient continues to have no disease progression and has no unacceptable toxicity; AND
- Prescriber must submit the following:
  - Current chart notes with documented response to treatment; AND
  - Current labs including CBC with differential and LFTs (CBCs should be monitored every other week for the first 2 cycles and prior to start of each cycle thereafter).

QUANTITY EDITS:

- #14/28 days for each strength

9. **ZOKINVY (lonafarnib)**

Discussion was tabled until additional efficacy data is available.

10. FRIENDLY REMINDERS:

1. Any questions concerning various Medicaid topics (e.g., Medicaid enrollment, prescription coverage, provider manuals, and billing policies) may be researched using one of the following links.
   - **https://medicaid.mmis.arkansas.gov/**
   - **https://humanservices.arkansas.gov/**
   - **https://arkansas.magellanrx.com/**

   Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member. For more information about PASSE, please refer to the website:
   https://humanservices.arkansas.gov/about-dhs/dms/passe/
   For questions about each PASSE organization, please refer to this website for contact information:
   https://humanservices.arkansas.gov/about-dhs/dms/passe/contact-us

2. **MAT (Medication Assisted Treatment) with buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*: *Treatment Improvement Protocol (TIP) Series 40*: "Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care. As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities."

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

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

4. **INCARCERATED PERSONS:**
   The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid clients who, on the date the prescription is filled, is incarcerated in a correctional or holding facility, including juvenile correctional facilities, and are detained pending disposition of charges, or are held under court order as material witnesses. If medications are requested for incarcerated Medicaid clients, including clients in a juvenile correctional facility, **the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment if billed to Medicaid**. Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

5. **Suboxone Film (buprenorphine/naloxone) once daily dosing:** as stated in the Suboxone Film package insert, the FDA approved dose for treating opioid addiction is prescribing the total daily dose as one single daily dose. "After treatment induction and stabilization, the maintenance dose of SUBOXONE sublingual film is generally in the range of 4 mg/1 mg

buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response. **The recommended target dosage of SUBOXONE sublingual film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose**. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage."

6. **REGARDING MANUAL REVIEW PA REQUESTS:** Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an exception to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the PDL, are all reviewed on a case-by-case basis through a manual review process. All manual review requests for prior authorization require, at a minimum, the prescriber to provide a letter explaining the medical necessity for the requested drug along with all written documentation to substantiate the medical necessity, e.g., chart notes, pharmacy printouts for cash, printout of private insurance paid drugs, lab results, etc. **Please note that starting the requested drug, including long-acting injectable antipsychotic agents, through either inpatient use, the use of office "samples", or by any other means, prior to a prior authorization request being reviewed and approved by the Medicaid Pharmacy Program does not necessitate Medicaid Pharmacy Program approval of the requested drug.**

7. **REGARDING EMERGENCY OVERRIDE**: In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires prior authorization (e.g., a drug that requires a clinical PA or requires a PA for a non-preferred drug). **This provision applies only in an emergency when the MMA Prescription Drug Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC clients and once per 60 days per drug class for LTC clients.

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

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

   Non-controlled drugs:
   The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA, and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits or an approved PA must be in the system for the client for the higher dose or an early refill PA will not be approved.

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

9. **REFILL TOO SOON ACCUMULATION LOGIC:** When a pharmacy refills a prescription claim early, the Medicaid system began adding together the accumulated "early days" filled. Each prescription is tracked by the Generic Sequence Number (GSN), which means the drug claim is the same generic name, same strength, and same dosage form, rather than tracking by prescription number or NDC.

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

.

   Controlled drugs:

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

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

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

    < 18 YEARS OF AGE:
    Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Clients have an ongoing requirement for labs for metabolic monitoring every 6 months. When any provider sends a patient, who is less than 18 years of age for the required metabolic labs for the antipsychotic agents, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.

    For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form may be found at the following link. https://arkansas.magellanrx.com/client/docs/rxinfo/MedInformedConsent.pdf

    < 10 YEARS OF AGE:
    Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) for all new starts on an antipsychotic agent, including a change in the chemical entity for children currently on an antipsychotic agent. All documentation, chart notes, signed informed consent, and required lab work must be submitted, and the manual review will be performed by the Medicaid Pharmacy Program psychiatrist.

12. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID CLIENTS WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that client can be billed using the client's Medicaid ID. If medications are needed to treat remaining family members, each prescription must be billed accordingly to each family member's Medicaid ID number. Sanctions may be imposed against a provider for engaging in conduct that defrauds or abuses the Medicaid program. This could include billing a child's medication to a parent's Medicaid ID number and vice-versa.

13. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:** AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to $9 for Brand Drugs and $10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website: https://arkansas.magellanrx.com/provider/documents/ A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website: https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

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

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

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

An added benefit of viewing the Medicaid Pharmacy Program Provider Memo online is the search feature, which will allow a more accessible and efficient user experience. To use this feature, use the shortcut by pressing the Ctrl + F keys, enabling a keyword search. Starting with the January 2018 memo, the online versions of the Provider Memos will also contain active hyperlinks in the Table of Contents. To activate these hyperlinks, open the Provider Memo, hover the mouse over the Table of Contents, press the Ctrl key until the mouse cursor ("hand") appears, then place the cursor on the item desired and click the mouse. The hyperlink in the Table of Content will then redirect to the corresponding chapter of the Provider Memo.

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.