Arkansas Medicaid Prescription Drug Program
Prior Authorization Criteria for Select Oncology Medications

Drug/Drug Class:	Oncology Medication (pharmacy claim) designated with an asterisk* on the PA form
First Implementation Date:	Varies
Updated PDL:	N/A
Updated Criteria:	04/16/2025
Status Criteria:	Criteria Revision New Criteria

NOTE: New-to-market oncology medications will follow the **Pharmacy Oncology Drug Management Policy** unless reviewed by the Drug Utilization Review (DUR) Board for specific criteria. If specific criteria has been DUR Board approved, this memo will be updated to include that information.

POINT-OF-SALE EDITS—if criteria is met, no prior authorization request will be needed.

- **ARIMIDEX® (anastrazole)**
  - Medical history for female with breast cancer billed in the past 3 years
  - Claim will deny if a diagnosis of infertility is found in Medicaid history
- **FEMARA® (letrozole)**
  - Medical history for female with breast cancer billed in the past 3 years
  - Claim will deny if a diagnosis of infertility is found in Medicaid history

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PRIOR AUTHORIZATION CRITERIA

- The following medications have specific criteria as approved by the Arkansas Medicaid Drug Utilization Review (DUR) Board/ Drug Review Committee (DRC).
- The Oncology Medicaid Prior Authorization Fax Form must be completed. Forms & Documents - Arkansas (primetherapeutics.com)

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1. GOMEKLI (mirdametinib) 1 mg & 2 mg capsules and 1 mg tablet for suspension (Effective 4/16/2025)

GOMEKLI is indicated for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia

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- Beneficiary must be diagnosed with neurofibromatosis type 1 (NF1) and have symptomatic plexiform neurofibromas (PN) not amenable to complete resection **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.

- Beneficiary must have at least **ONE** measurable PN **AND** either a positive genetic test for NF1 **OR** have at least **ONE** other diagnostic criteria listed below:
  - 6 or more café'-au-lait macules; **OR**
  - Freckling in axilla or groins; **OR**
  - Optic glioma; **OR**
  - 2 or more Lisch nodules; **OR**
  - Distinctive body lesion; **OR**
  - First-degree relative with NF1

- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Diagnosed with retinal vein occlusion (RVO) or retinal pigment epithelium detachment (RPED)
  - Has left ventricular ejection fraction (LVEF) < 55% at baseline, or has an absolute decrease in LVEF 20% or greater from baseline after treatment begins
  - Is pregnant
  - Has uncontrolled hypertension
  - History of glaucoma
  - Alanine transaminase (ALT) > 2X ULN
  - Is unable to tolerate GOMEKLI after one dose reduction

- Prescriber must submit the following:
  - Current chart notes with status of plexiform neurofibromas
  - Current baseline left ventricular ejection fraction (LVEF)
  - Previous therapies tried including any surgery
  - Documentation of comprehensive ophthalmic assessment
  - Current body surface area (BSA) for dose determination (Dosed 2 mg/m^2 twice daily for 21 days of each 28-day cycle)
  - Current labs including CBC, LFTs and creatine phosphokinase
  - Attestation that female patient of reproductive potential is using contraception
  - Medical necessity over Koselugo® (selumetinib)

- Initial PA will be for 3 months, renewal PAs may be approved for up to 6 months

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)

- Beneficiary should have an improvement with size or quantity of plexiform neurofibroma(s) after 9 months of treatment

- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy
  - Documentation of left ventricular ejection fraction (LVEF) every 3 months during the first year
  - Current body surface area for dose determination
  - Current labs including CBC, LFTs and creatine phosphokinase
  - Attestation that female patient of reproductive potential is using contraception

QUANTITY EDITS:

- 1 mg—#84/ 28 days (capsule available in package size of 42; tablets available in package sizes of 42 and 84)
- 2 mg—#84/ 28 days (available in package sizes of 42 and 84)

2. KOSELUGO (selumetinib) 10 mg and 25 mg capsules (Effective 7/15/2020)

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have at least one measurable PN measuring at least 3 cm AND either a positive genetic test for NF1 **OR** have at least one other diagnostic criterion listed below:
  - 6 or more café-au-lait macules; OR
  - Freckling in axilla or groin; OR
  - Optic glioma; OR
  - 2 or more Lisch nodules; OR
  - Distinctive bony lesion; OR
  - First-degree relative with NF1
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Does not meet approval criteria
  - If approved, beneficiary has disease progression or unacceptable toxicity and is unable to tolerate 2 dose reductions
  - Unable to swallow a whole capsule
  - BSA is < $0.55m^2$
  - Has retinal vein occlusion
  - Has symptomatic or Grade 3 or 4 decreased LVEF
  - Has Grade 4 diarrhea or Grade 3 or 4 colitis
  - Has rhabdomyolysis
  - Has severe hepatic impairment (Child-Pugh C)
  - Is pregnant
  - Is not using birth control when has reproductive potential
  - Requires strong or moderate CYP3A4 inducers
  - Dose should be reduced for required concomitant strong or moderate CYP3A4 inhibitors
- Provider should submit the following:
  - Current chart notes with status of plexiform neurofibromas
  - Current baseline left ventricular ejection fraction (LVEF)
  - Documentation of comprehensive ophthalmic assessment
  - Current labs including serum CPK, baseline INR, CBC, and LFTs
    - ANC ≥ 1500/µL
    - Hemoglobin ≥ 9g/dl
    - Platelets ≥ 100,000/µL
  - Current body surface area (BSA)—no recommended dosage for recipients with BSA < $0.55m^2$
  - Prescriber should provide plan for monitoring patients that require coadministration with vitamin-K antagonists or platelet antagonists
- Initial PA for 3 months

RENEWAL REQUIREMENTS

- Provider should submit the following:
  - Documentation of ejection fraction assessed every 3 months for the first year

  - Documentation of current labs including serum CPK, INR, CBC and LFTs
  - Current chart notes with documentation of response to therapy
  - Documentation of current BSA
  - Current required dosage
- Beneficiary should continue contraception unless has no reproductive potential
- Beneficiary should show improvement with the plexiform neurofibromas.

QUANTITY EDITS
- 10 mg capsule — #270/30 days
- 25 mg capsule — #120/30 days

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3. REZUROCK (belumosudil) 200 mg tablet (Effective 10/20/2021)

APPROVAL CRITERIA
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary of reproductive potential should use effective contraception
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Does not meet approval criteria
  - Is pregnant
  - If approved, demonstrates disease progression
  - Develops hepatotoxicity while on the medication with either Grade 4 AST or ALT (20X ULN) or Grade 3 or 4 bilirubin (3X ULN)
  - Has the following baseline labs
    - Platelets < 50 X 10^9 /L
    - ANC < 1.5 X 10^9 /L
    - AST or ALT > 3X ULN
    - Total bilirubin > 1.5X ULN
    - eGFR < 30 mL/min/1.73m^2
    - FEV1 ≤ 39% (patients with pulmonary manifestations)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with response

- Current labs including CBC with differential, LFTs, and CMP
- Negative pregnancy test for female recipient of reproductive potential

RENEWAL REQUIREMENTS

- Beneficiary demonstrates an improvement in baseline symptoms associated with GVHD

- Prescriber must submit the following:
  - Current chart notes
  - Response to treatment
  - Current labs including CBC with differential, LFTs, and CMP

QUANTITY EDITS:

- #30/ 30 days

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4. TURALIO (pexidartinib) 125 mg capsule (Effective 10/16/2019)

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication

- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia

- 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 **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.

- Provider and beneficiary must be enrolled in REMS program

- Beneficiary should not be approved or continue this therapy with any of the following:
  - Does not meet approval criteria
  - Is pregnant or breastfeeding
  - If cannot tolerate dose of 200 mg twice daily
  - Develops hepatoxicity
    - 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
  - Requires concomitant proton pump inhibitors
  - Requires concomitant strong CYP3A inhibitor (e.g., itraconazole) or uridine diphosphoglucuronosyltransferase (UGT) inhibitor (e.g., probenecid)—if unavoidable, reduce Turalio® dose
  - Has active or chronic infection with hepatitis C virus, hepatitis B virus or human immunodeficiency virus

- Provider must submit the following:

- Current chart notes with description of current range of motion and treatment history (if applicable)
- MRI results confirming diagnosis
- Medical necessity of Turalio® over surgery and/or radiation
- Current 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)
  - Renal function including serum creatinine and BUN
  - CBC with differential
- Documentation of stable prescription of analgesic regimen which can include opioids, anti-inflammatory medications or corticosteroids for at least 2 weeks with continued pain and mobility difficulties
- Attestation that provider counseled sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control
- Physical therapy notes if available; if not receiving PT, provider should explain rationale

- PA's approved month-to-month for at least first 3 months to monitor labs

RENEWAL REQUIREMENTS

- Beneficiary is compliant on therapy

- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs, CBC with differential and renal function which must fall within manufacturer's guidelines for renewal
  - Documentation of response to therapy with decrease in tumor size and/or documentation of improvement in range of motion
  - Reevaluation for surgery eligibility.

QUANTITY EDITS:

- #120 per 30 days

DATE:	SUMMARY OF CHANGES:	UPDATED BY:
07/01/2024	DUR BOARD REVIEW FOR ONCOLOGY MED SUMMARY	DUR BOARD
04/16/2025	DUR BOARD REVIEW FOR GOMEKLI	DUR BOARD