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:	10/16/2025	
Status Criteria:	atus Criteria: Criteria Revision	
	New Criteria	

<u>NOTE:</u> 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
 - o Claim will deny if a diagnosis of infertility is found in Medicaid history

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. <u>Forms & Documents -</u> Arkansas (primetherapeutics.com)

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

- Beneficiary must be diagnosed with neurofibromatosis type 1 (NF1) and have symptomatic plexiform neurofibromas (PN) not amenable to complete resection <u>OR</u> a diagnosis consistent with any new FDAapproved 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:
 - o 6 or more café'-au-lait macules; OR
 - o Freckling in axilla or groins; OR
 - Optic glioma; OR
 - o 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
 - o Is unable to tolerate GOMEKLI after one dose reduction
- Prescriber must submit the following:
 - o Current chart notes with status of plexiform neurofibromas
 - Current baseline left ventricular ejection fraction (LVEF)
 - Previous therapies tried including any surgery
 - o Documentation of comprehensive ophthalmic assessment
 - Current body surface area (BSA) for dose determination (Dosed 2 mg/m² twice daily for 21 days of each 28-day cycle)
 - o 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
 - o 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 & 25 mg capsules and 5 mg & 7.5 mg sprinkle 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
 - o 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
 - BSA is < 0.55m²
 - Has retinal vein occlusion
 - Has symptomatic or Grade 3 or 4 decreased LVEF
 - Has Grade 4 diarrhea or Grade 3 or 4 colitis
 - Has rhabdomvolvsis
 - 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
 - o 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 < 0.55m²
 - 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
- 5 mg sprinkle cap #600/30 days
- 7.5 mg sprinkle cap #360/30 days

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 <u>OR</u> 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
 - o 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 10⁹ /L
 - ANC < 1.5 X 10⁹ /L
 - AST or ALT > 3X ULN
 - Total bilirubin > 1.5X ULN
 - eGFR < 30 mL/min/1.73m²
 - FEV1 ≤ 39% (patients with pulmonary manifestations)

- Prescriber must submit the following:
 - Current chart notes
 - Documentation of previous therapies tried with response
 - o 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

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 <u>OR</u> 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
 - o 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, antiinflammatory 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:
 - o 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:

#120/30 days

DATE:	SUMMARY OF CHANGES:	UPDATED BY:
	DUR BOARD REVIEW FOR ONCOLOGY MED SUMMARY	DUR BOARD
	DUR BOARD REVIEW FOR GOMEKLI	DUR BOARD
10/16/2025	KOSELUGO SPRINKLE CAPSULE ADDED	DHS & PRIME