



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/11/2026

Pasatru™ (garetosmab-grts)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Diagnosis of fibrodysplasia ossificans progressiva (FOP) confirmed by genetic testing showing an ACVR1 mutation
 - d. Not to be used in combination with Sohonos® (palovarotene)
 - e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: Align with FDA recommended dosing
 - b. Authorization Period: One year at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- FOP is a rare connective tissue disorder characterized by severe, progressive HO of soft tissues that spans joints and results in an ectopic skeleton. FOP is caused by mutations in the ACVR1/ALK2 gene on chromosome 2q24, which encodes activin A receptor type I/activin-like kinase 2, a bone morphogenetic protein type I receptor. Definitive diagnosis requires genetic confirmation with specific molecular genetic studies that detect missense mutations or "in frame" deletions in the protein-encoding region of the ACVR1 gene. Consultation with a clinical geneticist is

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

recommended before genetic testing. Patients with FOP generally appear normal at birth except for bilateral malformation of the great toes (hallux valgus). Sporadic, painful episodes of rapidly progressive soft tissue swelling ("flare-ups") typically begin during the first decade of life. The soft tissue swelling may resolve but more often transforms skeletal muscles, tendons, ligaments, fascia, and aponeuroses into ribbons, sheets, or plates of heterotopic bone. Flare-ups may be precipitated by soft tissue injury, intramuscular injection, surgical incisions, falls, muscular stretching, or viral illness. FOP is a very rare genetic disorder with approximately 400 people affected in the U.S. and an estimated 800-900 confirmed cases worldwide.

- FOP is accelerated by trauma and avoiding deep tissue trauma, including intramuscular injections, is one way to prevent flare-ups and HO. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations from the international clinical council (ICC) on FOP was most recently updated in May 2022 and has recommendations including the use of corticosteroids, COX-1 inhibitors and NSAIDs, and topical analgesics to alleviate symptoms. The following options have low levels of evidence and are merely suggestions in a space that previously had no approved therapies. Mast cell inhibitors may be used to reduce the intense muscle edema, fibroproliferation and angiogenesis of FOP flare-ups, however the optimal use of such medications and their potential long-term efficacy in FOP is presently unknown. Bisphosphonates anecdotally seem to decrease flare-up symptoms in patients. Imatinib has been used to help with flare-ups. Presently, there is no definitive evidence that imatinib prevents or ameliorates flare-ups in FOP; however, early clinical observations support the implementation of clinical trials of imatinib in children with uncontrolled FOP flare-ups. Muscle relaxants may help to decrease muscle spasm and maintain more functional activity even in the setting of an evolving FOP lesion and may especially be true for painful flare-ups involving the limbs. In July of 2024 the ICC on FOP updated the medical management of fibrodysplasia ossificans progressiva: current treatment considerations to include Sohonos. The state of a patient with FOP considering Sohonos, the potential benefits and risks, as detailed in the package insert, by the MOVE trial publication, and in subsequent publications, must be discussed in detail with the patient and the patient's medical team. Additional risks should be explicitly discussed, including potential effects on bone health (loss of bone mass), skin/mucosal dryness and complications, potential for eye complications, and the risk of fetal malformations in pregnancy. The ICC supports continued close long-term follow-up of these potential complications. Standard-of-care therapies, as recommended by the FOP Treatment Guidelines should still be used in combination with Sohonos as appropriate, and with guidance from the patient's medical team. A recommendation for garetosmab has not been included in these guidelines at this time.

References:

1. Regeneron Press Releases: Regeneron Announces Positive Phase 3 Trial in Adults with Ultra-Rare Genetic Disorder Fibrodysplasia Ossificans Progressiva (FOP), Demonstrating that Garetosmab Prevents Greater than 99% of Abnormal Bone Formation. September 17, 2025 <https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-positive-phase-3-trial-adults-ultra-rare/>
2. ClinicalTrials.gov. (2022-2026). A Study to Assess Safety, Tolerability and Efficacy of Garetosmab Versus Placebo Administered Intravenously (IV) in Adult Participants With Fibrodysplasia Ossificans Progressiva (FOP). Identifier: NCT05394116. <https://clinicaltrials.gov/study/NCT05394116>
3. ClinicalTrials.gov. (2022-2026). A Study to Examine the Safety, Tolerability and Effects on Abnormal Bone Formation of REGN2477 in Patients With Fibrodysplasia Ossificans Progressiva" (LUMINA-1), is a Phase 2 clinical trial evaluating the drug garetosmab for the treatment of Fibrodysplasia Ossificans Progressiva (FOP). Identifier: NCT03188666. <https://clinicaltrials.gov/study/NCT03188666>
4. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations from the international clinical council on FOP. April 2021 (updated May 2022). https://assets.nationbuilder.com/ifopa/pages/1043/attachments/original/1665444347/GUIDELINES__updated_May_2022.pdf?1665444347
5. International fibrodysplasia ossificans progressive association (ifopa). What is FOP? https://www.ifopa.org/what_is_fop accessed May 2026.

Policy History		
#	Date	Change Description
1.0	Effective Date: 06/11/2026	Preliminary Drug Review

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*