

Clinical Policy Title:	mirdametininib
Policy Number:	RxA.903
Drug(s) Applied:	Gomekli
Original Policy Date:	09/10/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Neurofibromatosis Type 1:

1. Diagnosis of Neurofibromatosis Type 1 with symptomatic, inoperable plexiform neurofibromas.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Neurofibromatosis Type 1:

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. *Neurofibromatosis 1 - symptoms, causes, treatment: Nord*. National Organization for Rare Disorders. (2025, May 6). <https://rarediseases.org/rare-diseases/neurofibromatosis-type-1-nf1/>
Accessed September 5, 2025
2. Moertel, C. L., Hirbe, A. C., Shuhaiber, H. H., & Bielamowicz, K. (2025, February 20). *Renue: A pivotal, phase iib trial of Mirdametininib in adults and children with symptomatic neurofibromatosis type 1-associated plexiform neurofibroma*. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*. <https://pubmed.ncbi.nlm.nih.gov/39514826/>
Accessed September 5, 2025
3. Center for Drug Evaluation and Research. (2025, February 11). *FDA approves mirdametininib for adult and pediatric patients with neurofibromatosis*, U.S. Food and Drug Administration. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-mirdametininib-adult-and-pediatric-patients-neurofibromatosis-type-1-who-have-symptomatic>
Accessed September 5, 2025

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	9/10/2025	09/10/2025
Policy reviewed	12/11/2025	12/11/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

