Clinical Policy Title:	pacritinib
Policy Number:	RxA.756
Drug(s) Applied:	Vonjo™
Original Policy Date:	4/18/2022
Last Review Date:	4/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Vonjo™ is a kinase inhibitor indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109 /L (1).

This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pacritinib (Vonjo™)	Myelofibrosis (MF)	200 mg orally twice daily	400 mg/day orally.

Dosage Forms

- Capsules: 100 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Myelofibrosis (must meet all):

1. Diagnosis of intermediate or high-risk primary MF or secondary myelofibrosis (post-polycythemia vera or post-essential thrombocytopenia);
2. Prescribed by or in consultation with a/an hematologist or oncologist;
3. Age ≥ 18 years;
4. Severe thrombocytopenia with a platelet count of ≥ 50 x 10^9/L;
5. Does does not exceed 400 mg/day orally.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Myelofibrosis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (reduction in spleen volume of 35% or more, symptom relief);
3. If request is for a dose increase, dose does not exceed 400 mg/day orally.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
MACE: Major Adverse Cardiac Events

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Jakafi™	20 mg orally twice daily	25 mg Orally twice daily
Hydroxyurea	500-100 mg daily	1000 mg daily
Inrebic	400 mg daily	400 mg daily

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only, and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Concomitant use of strong CYP3A4 inhibitors or inducers.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information
Major Adverse Cardiac Events (MACE): Risk may be increased in current/past smokers and patients with other cardiovascular risk factors. Monitor for signs, evaluate and treat promptly.

References

1. Vonjo™ Prescribing Information. Seattle, WA: CTI BioPharma Corp; February 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208712s000lbl.pdf. Accessed March 14, 2022.
2. Vonjo™ Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, Available at: http://online.lexi.com. Accessed March 14, 2022.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com Accessed March 14, 2022.

4. Pacritinib. Micromedex Solutions. Truven Health Analytics Inc. Ann Arbor, MI. Available at https://www.micromedexsolutions.com. Accessed March 15, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/15/2022	4/18/2022