Drug Policy:

Doptelet™ (avatrombopag)

POLICY NUMBER UM ONC_1334	SUBJECT Doptelet™ (avatrombopag)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 06/13/18, 05/08/19, 07/10/19, 12/11/19, 08/12/20, 08/11/21, 11/15/21, 05/11/22, 07/13/22, 04/12/23, 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 06/13/18, 05/08/19, 07/10/19, 12/11/19, 08/12/20, 08/11/21, 11/15/21, 05/11/22, 07/13/22, 04/12/23, 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Doptelet (avatrombopag) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Idiopathic Thrombocytopenia Purpura (ITP)

1. The member has a diagnosis of relapsed/refractory chronic ITP AND
2. The member has had an insufficient response to (defined by failure of platelet count to increase and stay above 30 x 10^9/L) or has an intolerance or contraindication to corticosteroids AND
3. Platelet count less than 30,000 10^9/L prior to start of therapy.

C. Thrombocytopenia in Chronic Liver Disease

1. Doptelet (avatrombopag) may be used as a single agent if the following criteria are satisfied:
   a. The member has chronic liver disease AND
   b. A mean baseline platelet count of less than 50 x 10^9/L AND
   c. The member is scheduled to undergo an invasive procedure.

III. EXCLUSION CRITERIA

A. Disease progression defined as a lack in rise of platelet counts, from baseline, after 4 weeks at the maximum tolerated dose.

B. Use after failure with Mulpleta (lusutrombopag) for thrombocytopenia in chronic liver disease.

C. Dosing exceeds single dose limit of Doptelet (avatrombopag) 60 mg (for chronic liver disease) or 40 mg (for chronic ITP).

D. Treatment with Doptelet (avatrombopag) exceeds the maximum limit of 15 (20 mg) tablets per month (for chronic liver disease) or 60 (20 mg) tablets per month (for chronic ITP).

E. Dosing exceeds the treatment duration limit of 5 days (for chronic liver disease).

F. Investigational use of Doptelet (avatrombopag) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
   1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
   2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
   3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
   4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
   5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
   6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
   7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Doptelet prescribing information. AkaRx, Inc., Durham, North Carolina 2023.

B. Clinical Pharmacology Elsevier Gold Standard 2023.

C. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

F. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

G. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.