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	**APPROVAL DATE** December 11, 2019	**EFFECTIVE DATE** December 11, 2019	**COMMITTEE APPROVAL DATES** (latest version listed last) 06/13/18, 05/08/19, 07/10/19, 12/11/19	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Doptelet (avatrombopag) usage in the supportive treatment of cancer.

II. DEFINITIONS

Doptelet (avatrombopag): a thrombopoietin (TPO) receptor agonist that stimulates proliferation and differentiation of megakaryocytes from bone marrow progenitor cells resulting in an increased production of platelets. Avatrombopag does not compete with TPO for binding to the TPO receptor and has an additive effect with TPO on platelet production.

Doptelet (avatrombopag) is FDA approved for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Doptelet (avatrombopag) is available in 20 mg tablets.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Doptelet (avatrombopag) may be considered medically necessary when any of the following selection criteria are met:

1. **Thrombocytopenia**
    a. The member has hepatocellular cancer and chronic liver disease with a Model For End-stage Liver Disease (MELD) score less than or equal to 24 **AND**
    b. A mean baseline platelet count of less than 50 x 10^9/L **AND**
    c. The member is at high risk for bleeding who is scheduled to undergo a procedure.

Exclusion Criteria: Doptelet (avatrombopag) is not considered medically necessary when any of the following selection criteria are met:

1. Doptelet (avatrombopag) is being used after disease progression with the same regimen.

2. Concurrent use with heparin, warfarin, nonsteroidal anti-inflammatory drugs (NSAID), aspirin, verapamil, antiplatelet therapy with ticlopidine or glycoprotein IIb/IIIa antagonists (e.g., tirofiban), or erythropoietin stimulating agents.
3. The member has history of arterial or venous thrombosis.
4. Dosing exceeds single dose limit of Doptelet (avatrombopag) 60 mg.
5. Dosing exceeds the treatment duration limit of 5 days.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Doptelet (avatrombopag) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration: 60 mg PO once daily for 5 days if platelet count is less than 40 x 109/L or 40 mg PO once daily for 5 days if platelet count is 40 to 49 x 109/L beginning 10 to 13 days prior to the scheduled procedure. Patients should undergo their procedure 5 to 8 days after the last dose.**
2. **Dosage Adjustments: Dosage adjustments are not required for renal or hepatic impairment.**
3. **Monitoring**
    a. Improvement in platelet counts is indicative of efficacy.
    b. Platelet counts: Prior to administration and on the day of the procedure

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Doptelet prescribing information. AkaRx, Inc., Durham, North Carolina 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.

VIII. ADDENDUM

1. **Preferred product(s) for Arizona Health Care Cost Containment System (AHCCCS), Arizona's Medicaid agency: Nplate/oral Promacta**

   For AHCCCS members: when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy for a list of NON-preferred products.