JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS036
		Effective Date	10/01/2006
		Review Date	09/12/2023
	Subject **Thrombopoietin receptor agonists: Promacta,Tavalisse, Doptelet, Mulpleta**	*Revision Date*	07/15/2020
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Doptelet, Mulpleta, Promacta, Tavalisse

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I. POLICY

A. Promacta (eltrombopag), Tavalisse (fostamatinib), Doptelet (avatrombopag), and Mulpleta (lusutrombopag) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Promacta** (Eltrombopag) may be approved for patients who meet the following criteria:
   1. Chronic immune idiopathic thrombocytopenia(ITP)
      A. Patient is 1 year of age or older, and **one** of the following:
         i. Documented diagnosis of chronic ITP with platelet count less than 30 x 10^9/L AND insufficient response to corticosteroids, immunoglobulin, or splenectomy **OR**
         ii. Documented diagnosis of chronic ITP with platelet count between 30 x 10^9/L and 50 x 10^9/L AND insufficient response to corticosteroids or immunoglobulin with significant mucous membrane bleeding **OR**
         iii. Documented diagnosis of chronic ITP with platelet count between 30 x 10^9/L and 50 x 10^9/L AND insufficient response to corticosteroids or immunoglobulin with risk factors for bleeding (such as, but no limited to, hypertension, peptic ulcer disease, anticoagulation, recent surgery, etc.)
   2. Thrombocytopenia associated with Hepatitis C Infection
      A. Patient is 18 years of age or older
      B. Documented diagnosis of chronic hepatitis C-associated thrombocytopenia AND documentation that the patient will be initiated and maintained on interferon-based hepatitis C therapy

3. Aplastic Anemia
   A. For use as first-line treatment of severe aplastic anemia
      i. Patient is 2 years of age or older
      ii. Documented diagnosis of severe aplastic anemia AND documentation that the patient with be on a concurrent regimen of standard immunosuppressive therapy
   B. For use as refractory treatment of severe aplastic anemia
      i. Patient is 18 years of age or older
      ii. Document diagnosis of severe aplastic anemia with insufficient response to immunosuppressive therapy

B. **Tavalisse** (Fostamatinib) may be approved for patients who meet the following criteria:
   1. 18 years of age or older and meeting all of the following:
      A. Documented diagnosis of chronic immune idiopathic thrombocytopenia(ITP) with platelet count less than 30 x 10^9/L AND insufficient response to TWO of the following therapies:
         i. corticosteroids
         ii. immunoglobulin
         iii. splenectomy
         iv. Thrombopoietin receptor agonists (Nplate or Promacta)

C. **Doptelet** (avatrombopag) may be approved for patients who meet the following criteria:
   1. Thrombocytopenia associated with chronic liver disease
      A. 18 years of age or older and meeting all of the following:
         i. Documented diagnosis of thrombocytopenia and chronic liver disease with platelet count less than 50 x 10^9/L
         ii. Documentation that the patient will be undergoing a procedure within 10 to 13 days after starting Doptelet therapy
         iii. Documented insufficient response to the following therapies:
            a. corticosteroids
            b. immunoglobulin
         iv. Request duration of use is no more than 5 days
   2. Chronic immune idiopathic thrombocytopenia (ITP)
      A. 18 years of age or older and meeting all of the following:
         i. Documented diagnosis of chronic immune idiopathic thrombocytopenia(ITP) with platelet count less than 30 x 10^9/L AND insufficient response to TWO of the following therapies:
            a. corticosteroids
            b. immunoglobulin
            c. splenectomy
            d. Thrombopoietin receptor agonists (Nplate or Promacta)

D. **Mulpleta** (Lusutrombopag) may be approved for patient who meet the following criteria:
   1. 18 years of age or older and meeting all of the following:
      A. Documented diagnosis of thrombocytopenia and chronic liver disease with platelet count less than 50 x 10^9/L
      B. Documentation that the patient will be undergoing a procedure within 8 to 14 days after starting Mulpleta therapy
      C. Documented insufficient response to the following therapies:
         i. corticosteroids
         ii. immunoglobulin
      D. Request duration of use is no more than 7 days

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval for Promacta will be restricted to 1 month of therapy at dose less than or equal to the maximum recommended dose.
   1. Approval for continuation of therapy can be extended in 6-month intervals at dose less than or equal to the maximum recommended dose with clinical documentation supporting one of the following:
      a. Patient's platelet count has increased to ≥50 x 10^9/L in response to Promacta.
      b. Patient's platelet count has not increased to ≥50 x 10^9/L, but is expected to achieve platelet count to ≥50 x 10^9/L with an additional 6-week course of therapy.

B. Initial approval for Tavalisse will be restricted to 3 months of therapy at dose less than or equal to the maximum recommended dose.
   1. Approval for continuation of therapy can be extended in 6-month intervals at dose less than or equal to the maximum recommended dose with clinical documentation showing the following:
      a. Patient's platelet count has increased to ≥50 x 10^9/L in response to Tavalisse
      b. Prescriber is monitoring liver enzymes, CBC, and blood pressure routinely during therapy

C. Approval for Doptelet will be as follows:
   1. Thrombocytopenia associated with chronic liver disease: coverage will be restricted to a 5-day supply duration with the following dosing restrictions:
      a. Platelet count less than 40 x 10^9/L : 60mg (3 tablets) once daily
      b. Platelet count between 40 and less than 50 x 10^9/L: 40mg (2 tablets) once daily
   2. Chronic immune idiopathic thrombocytopenia:
      a. Initial coverage will be restricted to 3 months of therapy at dose less than or equal to the maximum recommended dose.
      b. Continuation of therapy can be extended in 6-month intervals at dose less than or equal to the maximum recommended dose with clinical documentation showing the following:
         I. Prescriber is monitoring liver enzymes, CBC, and blood pressure routinely during therapy
         II. Patient's platelet count has increased to ≥50 x 10^9/L in response to therapy

D. Approval for Mulpleta will be restricted to a 7-day supply duration, at 3mg once daily

IV. EXCLUSIONS

A. If the request is for a diagnosis not listed above, a letter may be sent to the requesting physician to provide additional information.

B. Promacta will not be approved for:
   1. Treatment in order to normalize platelet counts
   2. Treatment of myelodysplastic syndrome(MDS)
   3. Treatment of chronic hepatitis C-associated thrombocytopenia that does not prevent initiation or maintenance of optimal interferon-based therapy
   4. Concomitant use with direct-acting antiviral medication without interferon for chronic hepatitis C infections management
   5. Concomitant therapy with any other thrombopoietin receptor agonists
   6. Initial therapy for patients chronic ITP without a clinical condition and whose degree of thrombocytopenia does not increase the risk for bleeding (platelet count greater than or equal to 50 x 10^9/L)
   7. Patients who have failed to achieve platelet counts greater than or equal to 50 x 10^9/L after 8 weeks of therapy

C. Tavalisse will not be approved for:
   1. Treatment in order to normalize platelet counts
   2. Treatment of myelodysplastic syndrome(MDS)
   3. Treatment of chronic hepatitis C-associated thrombocytopenia that does not prevent initiation or maintenance of optimal interferon-based therapy
   4. Concomitant therapy with any other thrombopoietin receptor agonists
   5. Initial therapy for patients chronic ITP without a clinical condition and whose degree of thrombocytopenia does not increase the risk for bleeding (platelet count greater than or equal to 50 x 10^9/L)
   6. Patients who have failed to achieve platelet count greater than or equal to 50 x 10^9/L after 12 weeks of therapy

D. Doptelet will not be approved for:
   1. Treatment in order to normalize platelet counts
   2. Concomitant therapy with any other thrombopoietin receptor agonists
   3. Patients undergoing neurosurgical interventions, thoracotomy, laparotomy or organ resection
   4. Therapy for patients whose degree of thrombocytopenia does not increase the risk for bleeding (platelet count greater than or equal to 50 x 10^9/L)

E. Mulpleta will not be approved for:
   1. Treatment in order to normalize platelet counts
   2. Concomitant therapy with any other thrombopoietin receptor agonists
   3. Patients undergoing neurosurgical interventions, thoracotomy, laparotomy or organ resection
   4. Patients with a history of splenectomy, partial splenic embolization, or thrombosis
   5. Patients with Child-Pugh class C liver disease, absence of hepatopetal blood flow, or a prothrombotic condition other than chronic liver disease
   6. Therapy for patients whose degree of thrombocytopenia does not increase the risk for bleeding (platelet count greater than or equal to 50 x 10^9/L)

F. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

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2. Tavalisse [prescribing information]. Rigel Pharmaceuticals, Inc. San Francisco, CA, April 2018
3. Doptelet [prescribing information]. Dova Pharmaceuticals, Inc. Durham, NC, June 2021
4. Mulpleta [prescribing information]. Shionogi, Inc. Florham Park, NJ, July 2018
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VI. APPROVALS

Signature on file at JHHC

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DATE OF REVISION	SUMMARY OF CHANGE
07/20/2016	Removed background information, updated indications for Promacta, updated exclusion criteria, clarified authorization criteria, and made minor criteria edits
07/21/2017	Promacta indication update to include new approved age range for treatment
07/27/2017	Updated Exclusions section regarding physician samples
07/18/2018	Added clinical criteria for Tavalisse
10/17/2018	Added clinical criteria for Doptelet
01/16/2019	Added clinical criteria for Mulpleta; removed Nplate from policy
03/07/2019	Clarified the coverage criteria for Promacta based on FDA-approved prescribing information
07/09/2019	Updated criteria for Doptelet based on FDA-approved new indication
07/15/2020	Clarified the authorization and limitations with Doptelet

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