imatinib (Gleevec®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO128

Description

Imatinib (Gleevec) is an orally administered protein-tyrosine kinase inhibitor that inhibits the bcr-abl tyrosine kinase to suppress proliferation and promote apoptosis of cancer cells.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
imatinib	100 mg tablet	Chronic eosinophilic leukemia; Dermatofibrosarcoma protuberans, unresectable, recurrent, and/or metastatic; Gastrointestinal stromal tumor, Kit (CD117)-positive, adjuvant treatment; Gastrointestinal stromal tumor, Kit (CD117)-positive, unresectable or metastatic disease; Hypereosinophilic syndrome; Myelodysplastic syndrome, PDGFR gene rearrangement; Myelodysplastic syndrome, chronic, PDGFR gene rearrangement; Philadelphia chromosome-positive acute lymphoblastic leukemia, newly diagnosed, in combination with chemotherapy; Philadelphia chromosome-positive acute lymphoblastic leukemia, relapsed/refractory; Philadelphia chromosome positive chronic myelogenous leukemia, accelerated phase or blast crisis; Philadelphia chromosome positive chronic myelogenous leukemia, chronic phase, after failure of interferon-alpha therapy;	90 tablets/ 30 days
	400 mg tablet		30 tablets/ 30 days
imatinib (Gleevec)	100 mg tablet		90 tablets/ 30 days
	400 mg tablet		30 tablets/ 30 days

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		Philadelphia chromosome positive chronic myelogenous leukemia, chronic phase, newly diagnosed; Systemic mast cell disease, aggressive, D816V c-Kit mutation negative or unknown	

Initial Evaluation

I. Imatinib may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older for all indications except the following;
      1. Philadelphia chromosome-positive acute lymphoblastic leukemia, newly diagnosed, in combination with chemotherapy
      2. Philadelphia chromosome positive chronic myelogenous leukemia, chronic phase, newly diagnosed;
         AND
   B. Medication is prescribed by, or in consultation with, an oncologist **AND**
   C. Not used in combination with other oral oncolytic therapies (e.g., sunitinib [Sutent], regorafenib [Strivarga], bosutinib [Bosulif], nilotinib [Tasigna]); **AND**
   D. Generic imatinib is prescribed, unless generic has been tried and failed, is not tolerated or contraindicated [documentation required] (note: imatinib is the interchangeable AB-rated generic of Gleevec); **AND**
   E. A diagnosis of one of the following:
      1. **Chronic eosinophilic leukemia**
      2. **Dermatofibrosarcoma protuberans, unresectable, recurrent, and/or metastatic**
      3. **Gastrointestinal stromal tumor, Kit (CD117)-positive, adjuvant treatment**
      4. **Gastrointestinal stromal tumor, Kit (CD117)-positive, unresectable or metastatic disease**
      5. **Hypereosinophilic syndrome**
      6. **Myelodysplastic syndrome, PDGFR gene rearrangement**
      7. **Myelodysplastic syndrome, chronic, PDGFR gene rearrangement**
      8. **Philadelphia chromosome-positive acute lymphoblastic leukemia, newly diagnosed, in combination with chemotherapy**
      9. **Philadelphia chromosome-positive acute lymphoblastic leukemia, relapsed/refractory**
      10. **Philadelphia chromosome positive chronic myelogenous leukemia, accelerated phase or blast crisis**
      11. **Philadelphia chromosome positive chronic myelogenous leukemia, chronic phase, after failure of interferon-alpha therapy**
      12. **Philadelphia chromosome positive chronic myelogenous leukemia, chronic phase, newly diagnosed**
      13. **Systemic mast cell disease, aggressive, D816V c-Kit mutation negative or unknown**

II. Imatinib (Gleevec) is considered investigational when used for all other conditions, including but not limited to:
   A. Breast cancer
   B. Cervical cancer
   C. Graft-versus-host disease
   D. Malaria
   E. Melanoma
   F. Mesothelioma
   G. Multifocal leukoencephalopathy
   H. Multiple sclerosis
   I. Neurofibromas
   J. Non-Hodgkin's lymphoma
   K. Ovarian or peritoneal cancers
   L. Pancreatic cancer
   M. Renal cancers
   N. Sickle cell anemia
   O. Thyroid cancer

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Prescribed by, or in consultation with, an oncologist; **AND**
IV. Member has exhibited improvement or stability of disease with lack of disease progression; **AND**
V. For imatinib (Gleevec) brand: generic imatinib has been tried and failed, not tolerated, or is contraindicated [documentation required] (note: imatinib is the interchangeable AB-rated generic of Gleevec).

Supporting Evidence

I. Imatinib (Gleevec) is a tyrosine kinase inhibitor, indicated in a variety of disease states in adults, and two indications have been evaluated with treatment of imatinib (Gleevec) in pediatric patients. Dosing is indication specific, but ranges from 100 mg to 800 mg per day, with standard dosing ranging from 400 mg to 800 mg per day.. Dose adjustments may be warranted in the setting of toxicity or organ dysfunction/impairment. Imatinib (Gleevec) may be used as monotherapy or in addition to chemotherapy for certain indications. Use with other oral tyrosine kinase oncolytic therapies has not been evaluated for safety and/or efficacy to date.
II. Overarching indications include chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), gastrointestinal stromal tumor (GIST), eosinophilic leukemia and syndromes,

dermatofibrosarcoma protuberans, myelodysplastic syndromes, and systemic mast cell disease. An extensive number of clinical trials have been completed for imatinib (Gleevec).

III. Generic imatinib is available and is recognized as the AB-rated interchangeable generic to Gleevec. It provides better value and is a cost effective option compared to brand Gleevec with no known safety or efficacy differences at this time. Payment consideration for brand is reserved for those that have had inefficacy, intolerance, or contraindication to generic imatinib. Occurrence of toxicities known to be in the adverse event profile of imatinib (Gleevec), does not meet medical necessity for brand over generic exception. If toxicity occurs, consistent with the imatinib (Gleevec) adverse event profile, dose reduction or discontinuation may be appropriate.

Investigational or Not Medically Necessary Uses

I. Imatinib (Gleevec) has not been sufficiently evaluated for safety and/or efficacy and/or is in clinical trials for the following indications:
   A. Breast cancer
   B. Cervical cancer
   C. Graft-versus-host disease
   D. Malaria
   E. Melanoma
   F. Mesothelioma
   G. Multifocal leukoencephalopathy
   H. Multiple sclerosis
   I. Neurofibromas
   J. Non-Hodgkin's lymphoma
   K. Ovarian or peritoneal cancers
   L. Pancreatic cancer
   M. Renal cancers
   N. Sickle cell anemia
   O. Thyroid cancer

References

1. Gleevec [Prescribing Information]. East Hanover, NF. Novartis Pharmaceuticals Corp. September 2017.
2. U.S. National Library of Medicine clinical Trials Registry. Available at: https://clinicaltrials.gov. Accessed November 2019.
3. Orange Book: Approved Drug Products with therapeutic Equivalence Evaluations. U.S. Food & Drug Administration. Available at: https://www.accessdata.fda.gov/scripts/Cder/ob/search_product.cfm. Accessed November 2019.

Policy Implementation/Update:

Date Created	August 2008
Date Effective	August 2008
Last Updated	November 2019
Last Reviewed	02/2016, 03/2016, 05/2017, 11/2018, 11/2019

Action and Summary of Changes	**Date**
Prior authorization criteria transitioned to policy format, new indications added/specified, age edit added, addition of specialist provider, and limitation of dual oral therapy.	11/2019
Generic imatinib preferred therapy indicated for initial and continuation of therapy, unless medical necessity for brand met.	11/2018
Criteria questions rearranged and clarified.	08/2017
Criteria updated to prefer generic imatinib for initial approval.	05/2017
Criteria updated for new disease states.	02/2016