Medical Coverage Policy | Poteligeo (mogamulizumab-kpkc)

EFFECTIVE DATE: 08|01|2019
POLICY LAST UPDATED: 04|16|2019

OVERVIEW

Poteligeo ™ (mogamulizumab-kpkc) is for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

Poteligeo ™ (mogamulizumab-kpkc) will be approved when ALL of the following are met:

1. ONE of the following:
   a. There is documentation provided with the request (e.g. treatment start date, length of treatment, patient's clinical benefit from therapy) indicating that the patient is currently being treated with the requested agent

   OR

   b. The patient has a diagnosis of mycosis fungoides (MF) or Sézary syndrome AND ONE of the following
      i. BOTH of the following:
         1. The patient has had at least ONE prior systemic therapy

         AND

         2. The diagnosis is relapsed or refractory

      OR

      ii. The requested indication is supported by ALL requirements in either FDA labeling or NCCN 1 or 2A recommended use for the requested agent [i.e., this indication must be supported by ALL requirements in the FDA label or NCCN "Recommended Use" box (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)]

   OR

   c. The patient has another FDA labeled indication for the requested agent [i.e., this indication must be supported by ALL requirements in the FDA label (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy)]

   OR

   d. The patient has an NCCN 1 or 2A recommended indication for the requested agent [i.e., this indication must be supported by ALL requirements in the NCCN "Recommended Use" box (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)]

AND

2. The patient does NOT have any active infections

AND

3. The patient does NOT have active autoimmune disease

AND

4. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

5. The requested dose is within FDA labeled dosing [or supported in compendia (DrugDex 1 or 2a level of evidence)] for the requested indication

Length of Approval: 12 months or for duration of treatment as supported in FDA labeling or NCCN compendia, whichever is shorter

Poteligeo ™ (mogamulizumab-kpkc) will also be approved when the following are met:

1. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation supporting the requested therapeutic use (documentation must be provided and approval by the Clinical Review Pharmacist is required).

AND

2. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

Length of Approval: 12 months

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare.

POLICY STATEMENT

BlueCHiP for Medicare

Poteligeo ™ (mogamulizumab-kpkc) is medically necessary when the criteria above have been met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug medically necessary benefits/coverage.

BACKGROUND

Mycosis fungoides and Sézary syndrome

Cutaneous T-cell lymphomas (CTCLs) are a group of non-Hodgkin lymphomas (NHLs) of mature t-cells that primarily present in the skin, and at times progress to involve lymph nodes, blood and visceral organs. Mycosis fungoides (MF) is the most common subtype with primary cutaneous involvement and Sézary syndrome (SS) is an erythrodermic, leukemic variant of CTCK that is characterized by significant blood involvement and lymphadenopathy. MF accounts for about 50-70% of CTCLs while SS accounts for only 1-3% of CTCLs.

Early stage (IA to IIA) mycosis fungoides (MF) is treated with skin directed therapies rather than systemic therapies. The choice among skin-directed therapies is made based upon the physician's experience with these methods, staging of the disease, lesion characteristics, patient characteristics, and side effect profiles. In general, topical corticosteroids or topical nitrogen mustard are the preferred initial treatment options for Stage IA and for patients with stage IB or IIA initial treatment includes topical corticosteroids, topical nitrogen mustard, and/or ultraviolet B (UVB) therapy. For patients with rapidly progressive generalized, thickened plaques in whom a prompt response is needed, total skin electron beam therapy can be used as initial therapy rather than topical nitrogen mustard or UVB therapy alone.

Advanced stage (IIB to IV) MF is often a chronic or persistent disease with relapsing course. The main goals of therapy are long term disease control, prompt symptom relief, and management of life threatening (aggressive) disease. For patients that present in these advanced stages, there is no standard initial therapy, and experts differ in their preferred approach. Since most agents have a short duration of response after the

cessation of therapy, maintenance therapy that incorporates agents with low toxicity and preserves the immune response is usually preferred, even if these agents have a slower time to response or lower overall response rate than more toxic agents. In contrast, more potent therapy is required for cases with an aggressive clinical presentation. Allogeneic hematopoietic cell transplantation (HCT) following myeloablative or reduced intensity conditioning may result in durable remissions or meaningful "downstaging" in a subset of patients, perhaps due to a graft-versus-lymphoma effect. As experience with this modality grows, it is an option increasingly offered to selected patients with high-risk disease. A choice regarding the use of HCT must take into consideration the risk of treatment-related mortality and morbidity, including graft-versus-host disease (GVHD). In contrast, high-dose chemotherapy followed by autologous HCT is not recommended due to a uniformly high risk of relapse.4 The National Comprehensive Cancer Network (NCCN) states that allogeneic hematopoietic cell transplantation appears to be a promising therapeutic strategy in patients with advanced cutaneous T-cell lymphomas (which includes MF and Sézary syndrome) but further data from prospective studies are needed to establish the role of allogenic hematopoietic stem cell transplant in these patients.

Treatment for Sézary syndrome is similar to that for advanced MF, with some distinctive exceptions, including the use of extracorporeal photopheresis (ECP) and low dose alemtuzumab, and the need for adjuvant treatment to control pruritus. Given the leukemic blood involvement in Sézary syndrome, systemic treatments are generally required. Systemic therapy can be given alone, with skin-directed therapy, or with other systemic therapies. Most patients will relapse after initial treatment, and some patients have disease that is refractory to initial or subsequent therapy. There is no standard treatment for patients with relapsed or refractory Sézary syndrome.

CODING

BlueCHiP for Medicare

The following HCPCS code is covered when the medical criteria have been met:

C9038 Injection, mogamulizumab-kpkc, 1 mg

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, June 2019

REFERENCES

1. Poteligeo Prescribing Information. Kyowa Kirin Inc. August 2018.
2. National Comprehensive Cancer Network (NCCN). T-Cell Lymphomas. Version 5.2018.
3. Hoppe RT, Kim YH, Horowitz S. UpToDate Treatment of early stage (IA to IA) mycosis fungoides. Last updated September 2017.
4. Hoppe RT, Kim YH, Horowitz S. UpToDate Treatment of advanced stage (IIB to IV) mycosis fungoides. Last updated July 2017.
5. Kim EJ, Rook AH. UpToDate Treatment of Sézary syndrome. Last updated September 2018.