Mass General Brigham
Health Plan

Melanoma Agents
Imlygic (talimogene laherparepvec)
Kimmtrak (tebentafusp-tebn)
Effective 02/18/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Imlygic is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

Kimmtrak is indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

Imlygic (talimogene laherparepvec)
1. Diagnosis of unresectable melanoma
2. Prescriber is an oncologist
3. Requested quantity is ≤ 4 mL per treatment
4. Unresectable cutaneous, subcutaneous, or nodal lesions
5. Melanoma recurrent after initial surgery

Kimmtrak (tebentafusp-tebn)
1. Diagnosis of unresectable or metastatic uveal melanoma
2. Member is positive for HLA-A*02:01 genotype
3. Prescriber is an oncologist
4. Appropriate dosing
5. **ONE** of the following:
    a. Member is refractory to radiation therapy

b. Radiation therapy is not appropriate

Continuation of Therapy
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Initial authorizations will be granted for:
    a. Kimmtrak: 3 months
    b. Imlygic: 6 months.
2. Reauthorizations will be granted for:
    a. Kimmtrak: 4 months
    b. Imlygic: 6 months

References

1. Kimmtrak® [prescribing information]. Conshohocken (PA): Immunocore Commercial LLC.; 2022 Feb.
2. Imlygic® [package insert]. Thousand Oaks (CA); Amgen, Inc.; 2023 Feb.
3. Sosman JA. Molecularly targeted therapy for metastatic melanoma. In: Ross ME (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 May [cited 2022 Jun 8]. Available from http://www.utdol.com/utd/index.do. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf.
4. Hodi FS, O'Day SJ, McDermott DF, Weber RW, Sosman JA, Haanen JB, et al. Improved Survival with Ipilimumab in Patients with Metastatic. N Engl J Med. 2010 Aug;363(8):711-23.
5. Sosman JA. Cytotoxic Chemotherapy for Metastatic Melanoma. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 [cited 2022 Jun 8]. Available from: http://www.utdol.com/utd/index.do.
6. Garbe C, Eigentler TK, Keilholz U, Hauschild A, Kirkwood JM. Systematic Review of Medical Treatment in Melanoma: Current Status and Future Prospects. The Oncologist. 2011; 16:6-24.
7. Sosman JA. Immunotherapy of advanced melanoma with immune checkpoint inhibition. In: Ross ME (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Jul [cited 2021 Jul 7]. Available from http://www.utdol.com/utd/index.do.
8. Dummer R, Hauschild A, Guggenheim M, Jost L & Pentheroudakis. Melanoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 2010; 21 (Supplement 5): 194–7.

Review History
11/17/2021 – Created and Reviewed Nov P&T; alignment with the MassHealth Uniform formulary. Effective 01/01/2022
11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Effective 11/1/22. Guideline update to include off-label uses for Cotellic, Mekinist, Tafinlar and Zelboraf in members with glioma (BRAF mutation) and for Mekinist and Mektovi for members with low-grade serous carcinoma of the ovary, fallopian tube, or primary peritoneum. Clarified appropriate diagnosis and quantity limits on all agents within coverage guidelines. Effective 2/1/23. Updates include expanded indication for Mekinist and Tafinlar combination therapy for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation.
01/11/23 – Reviewed and updated for Jan P&T. Off label indications were combined into own section for: low grade/high grade glioma and low-grade serous carcinoma of the ovary, fallopian tube, primary peritoneum. Effective 3/1/23.
04/12/23 – Reviewed and updated for P&T. Added Kimmtrak®(tebentafusp-tebn). Updated references. Effective 5/1/23.

05/10/23 – Reviewed and updated for P&T. Added Imlygic to criteria through the medical benefit with PA. Effective 6/5/23
2/14/24 – Reviewed and updated for P&T. Kimmtrak will only be available on MB with PA. Added expanded indication of Mekinist in combination with Tafinlar for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. Age also updated for pediatric patients from 6 years of age to 1 year of age for both Mekinist and Tafinlar for unresectable or metastatic solid tumors. Criteria for expanded indication for Cotellic in the treatment of adults with histiocytic neoplasms, which include Erdheim-Chester disease, Rosai-Dorfman disease, and Langerhans cell histiocytosis added. Effective 3/4/24
1/2025 – Reviewed and updated for P&T. Separated out Rx vs MBO products. Kimmtrak and Imlygic remains while Rx products can be reviewed via MHDL. No clinical changes. Effective 2/18/25