Evolent Clinical Guideline 3133 for Imjudo™ (tremelimumab)

Guideline Number:	Applicable Codes	
Evolent_CG_3133		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
December 2022	June 2025	June 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Imjudo (tremelimumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Hepatocellular Carcinoma

- The member has unresectable hepatocellular carcinoma (Child-Pugh Class A score only and/or Barcelona Clinic Liver Cancer stage B or C) with no prior systemic treatment, including prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab) AND
- Imjudo (tremelimumab) will be used (for one cycle) as first line therapy in combination with Imfinzi (durvalumab) followed by continuation of Imfinzi (durvalumab).

The Barcelona Clinic Liver Cancer (BCLC) Staging System (60)

BCLC stage	ECOG PS	Liver function: Child-Pugh	Tumor stage
Very early stage (0)	0	A	Single ≤2 cm
Early stage (A)	0	A-B	Single ≤3, nodules ≤3 cm
Intermediate stage (B)	0	A-B	Multinodular
Advanced stage (C)	1-2	A-B	Vascular invasion, extrahepatic spread
Terminal stage (D)	3-4	C	Any

CHILD-PUGH SCORE

Chemical and Biochemical Parameters	Scores (Points) for Increasing Abnormality		
	1	2	3
Encephalopathy (grade)[1]	None	1–2	3–4
Ascites	Absent	Slight	Moderate
Albumin (g/dL)	>3.5	2.8–3.5	<2.8
Prothrombin time[2] Seconds over control INR	 <4 <1.7	 4–6 1.7–2.3	 >6 >2.3
Bilirubin (mg/dL) • For primary biliary cirrhosis	<2 <4	2–3 4–10	>3 >10

Class A = 5–6 points; Class B = 7–9 points; Class C = 10–15 points.

Non-Small Cell Lung Cancer (NSCLC)

- The member has not received prior systemic therapy for recurrent/metastatic or Stage IV NSCLC and the tumor is negative for EGFR and ALK, regardless of PD-L1 expression AND
- Imjudo (tremelimumab) will be used as first line therapy in combination with Imfinzi (durvalumab) and platinum-based chemotherapy for up to 4 cycles. This may be followed by maintenance therapy with Imfinzi (durvalumab), 1 dose of Imjudo (tremelimumab) and optional histology-based pemetrexed. [Maximum of 5 total doses of Imjudo (tremelimumab)].

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Disease progression while taking Imjudo (tremelimumab) or prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab).
- For Hepatocellular Carcinoma: Dosing exceeds single dose limit of Imjudo (tremelimumab) 300 mg (for weight greater than or equal to 30 kg) or 4 mg/kg (for weight less than 30 kg). Treatment exceeds one time dose administration of Imjudo (tremelimumab).
- For NSCLC: Dosing exceeds single dose limit of Imjudo (tremelimumab) 75 mg/kg (for weight 30 kg or more) or 1 mg/kg (for weight less than 30 kg). Treatment exceeds 5 doses/5 cycles of Imjudo (tremelimumab).
- Investigational use of Imjudo (tremelimumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

- Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
- Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
- Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9347 - Injection, tremelimumab-actl, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
June 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1469 Imjudo (tremelimumab) • Updated indication section • Updated references
October 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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