

Provider Administered Drugs – Site of Care (for Mississippi Only)

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[Instructions for Use](#)

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Related Policy
<ul style="list-style-type: none"> Ilumya® (Tildrakizumab-Asmn)

Application

This Medical Policy only applies to the state of Mississippi for the following medication:

- Ilumya™ (Tildrakizumab-asmn)

Coverage Rationale

This policy addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes:

- 19 Off Campus-Outpatient Hospital; and
- 22 On Campus-Outpatient Hospital

Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.

Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required):

- Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following:
 - The individual’s complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or
 - The individual’s documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; or
 - Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or
 - Difficulty establishing and maintaining patent vascular access; or
- Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to

acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or

- Initial infusion or re-initiation of therapy after more than 6 months; or
- Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy and both of the following
 - The prescriber is unable to infuse in the office setting
 - There are no ambulatory infusion suite options available for this member

Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care.

This policy applies to these specialty medications that require healthcare provider administration:

- Ilumya™ (Tildrakizumab-asmn)

Definitions

Site of Care: Choice for physical location of infusion administration. Sites of Care include hospital inpatient, hospital outpatient, physician office, ambulatory infusion suite, or home-based setting.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J3245	Injection, tildrakizumab, 1 mg

Clinical Evidence

Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications.

Clinical Practice Guidelines

American Academy of Allergy Asthma and Immunology

The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics: previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment.

References

Barfield E, Solomon A, Sockolow R. Inflammatory Bowel Disease: A Practical Approach. *Prac Gastroenterol* May 2016, 5:16-23.

Centers for Medicare & Medicaid Services: Place of Service Code Set. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html.

Phase I: 2010 NHIA Provider Survey Comprehensive Aggregate Analysis Report. National Home Infusion Association. 2011.

Policy History/Revision Information

Date	Summary of Changes
01/01/2023	<p>Template Update</p> <ul style="list-style-type: none">• Changed policy type classification from “Utilization Review Guideline” to “Medical Policy” <p>Definitions</p> <ul style="list-style-type: none">• Updated definition of “Site of Care” <p>Supporting Information</p> <ul style="list-style-type: none">• Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information• Archived previous policy version CS155MS.I

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.