Clinical UM Guideline

Subject:	Site of Care: Specialty Pharmaceuticals		
Guideline #:	CG-MED-83	**Publish Date:**	10/05/2022
Status:	Reviewed	**Last Review Date:**	08/11/2022

Description

This document provides clinical criteria for use of outpatient infusion therapy service in the hospital outpatient department or hospital outpatient clinic site of care for intravenous (IV) infusion and injectable therapy.

Note: In some plans, "level of care," "site of service" or another term such as "setting" or "place of service" may be the term used in benefit plans, provider contracts, or other materials instead of or in addition to "site of care" and, in some plans, these terms may be used interchangeably.

Note: Please see the following related documents for additional information:
- CG-SURG-10 Ambulatory or Outpatient Surgery Center Procedures
- CG-SURG-52 Site of Care: Hospital-Based Ambulatory Surgical Procedures and Endoscopic Services

Clinical Indications

Note: The medical necessity of the infused pharmacologic or biologic agent may be separately reviewed against the appropriate criteria. This guideline is for determination of the medical necessity of hospital outpatient site of care for the IV infusion and injectable therapy.

Medically Necessary:

An outpatient IV infusion or injectable therapy service in the hospital outpatient department or hospital outpatient clinic site of care for the use of an infused pharmacologic or biologic agent is considered **medically necessary** when **all** of the following are present:

A. The inherent complexity or risk of the infusion required by an individual is such that it can be performed safely and effectively only by or under the general supervision of skilled nursing personnel; **and**
B. The individual's medical status or therapy is such that it requires enhanced monitoring beyond that which would routinely be needed for infusion therapy; **and**
C. The potential changes in the individual's clinical condition are such that immediate access to specific services of a medical center/hospital setting, having emergency resuscitation equipment and personnel, and inpatient admission or intensive care is necessary, for example, the individual is at significant risk of sudden life-threatening changes in medical status based on clinical conditions including but not limited to:
    1. concerns regarding fluid overload status; **or**
    2. history of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic agent; **or**

Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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3. acute mental status changes.

Not Medically Necessary:

All other uses of outpatient IV infusion and injectable therapy services in the hospital outpatient department or hospital outpatient clinic site of care for the infusion of pharmacologic and biologic agents are considered **not medically necessary.**

Coding

Coding edits for medical necessity review are not implemented for this guideline. Where a more specific policy or guideline exists, that document will take precedence and may include specific coding edits and/or instructions. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Discussion/General Information

Infusion therapy (pharmacologic or biologic agents) has been proven to be safely and effectively administered in an office-based setting, infusion center or the home setting. Home-based infusion, when appropriate and available, may in some cases be supported by member preference (Chataway, 2006; Milligan, 2006; Riazi, 2011). Hospital outpatient administration of IV medications may be appropriate for complex infusions requiring direct observation or the minimization of certain treatment risks that require hospital based therapy when criteria are met.

The hospital outpatient department or hospital outpatient clinic is part of a hospital, but is designed for the treatment of outpatients; that is, individuals who do not require hospital admission.

References

Peer Reviewed Publications:

1. Chataway J, Porter B, Riazi A, et al. Home versus outpatient administration of intravenous steroids for multiple-sclerosis relapses: a randomized controlled trial. Lancet Neurol. 2006; 5(7):565-571.
2. Gutierrez-Aguirre CH, Ruiz-Arguelles G, Cantu-Rodriguez OG, et al. Outpatient reduced-intensity allogeneic stem cell transplantation for patients with refractory or relapsed lymphomas compared with autologous stem cell transplantation using a simplified method. Ann Hematol. 2010; 89(10):1045-1052.
3. Mank A, van der Lelie J, de Vos R, Kersten MJ. Safe early discharge for patients undergoing high dose chemotherapy with or without stem cell transplantation: a prospective analysis of clinical variables predictive for complications after treatment. J Clin Nurs. 2011; 20(3-4):388-395.
4. Milligan A, Hughes D, Goodwin S, et al. Intravenous enzyme replacement therapy: better in home or hospital? Br J Nurs. 2006; 15(6):330-333.

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5. Riazi A, Porter B, Chataway J, et al. A tool to measure the attributes of receiving IV therapy in a home versus hospital setting: the Multiple Sclerosis Relapse management Scale (MSRMS). Health Qual Life Outcomes. 2011; 9:80.
6. Teuffel O, Ethier MC, Alibhai SM, et al. Outpatient management of cancer patients with febrile neutropenia: a systematic review and meta-analysis. Ann Oncol. 2011; 22(11):2358-2365.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Allergy Asthma and Immunology. Guidelines for the site of care for administration of IGIV therapy. December 2011. Available at: http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/Guidelines-for-the-site-of-care-for-administration-of-IGIV-therapy.pdf. Accessed on June 24, 2022.
2. Basch E, Hesketh PJ, Kris MG, et al. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. J Clin Onc. 2011; 29(31):4189-4198.
3. Broyles AD, Banerji A, Barmettler S, et al. Practical guidance for the evaluation and management of drug hypersensitivity: Specific drugs. J Allergy Clin Immunol Pract. 2020; 8(95):S16-S116.
4. NCCN Clinical Practice Guidelines in Oncology®. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 24, 2022.
    - Antiemesis (V.2.2022). Revised March 23, 2022.
    - Prevention and Treatment of Cancer-Related Infections. (V.1.2022) Revised June 2, 2022.

Websites for Additional Information

1. National Home Infusion Association. About home and specialty infusion. Available at: https://www.nhia.org/about-infusion-therapy/. Accessed on. June 24, 2022.

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Infusion therapy
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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	08/11/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and Websites sections.
Reviewed	08/12/2021	MPTAC review. Updated reference and Websites sections.

Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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Revised	08/13/2020	MPTAC. Updated MN and NMN clinical indications to address "site of care" removing reference to level of care. Revised title to: *Site of Care: Specialty Pharmaceuticals*. Updated Description, References and Websites sections.
Reviewed	05/14/2020	MPTAC review. Updated References and Websites sections.
Reviewed	06/06/2019	MPTAC review. Updated Discussion, References and Websites sections.
	03/21/2019	Changed the document number from CG-DRUG-47 to CG-MED-83 with same title.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date". Updated References and Websites sections.
Reviewed	08/03/2017	MPTAC review. Formatting updated in clinical indications section. Updated References section.
Reviewed	08/04/2016	MPTAC review. Updated formatting in clinical indications section. Updated Discussion, References and Index sections.
Revised	11/05/2015	MPTAC review. Clarified medically necessary and not medically necessary statement. Updated Description and References sections.
New	08/06/2015	MPTAC review. Initial document development.

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Federal and State law, as well as contract language including definitions and specific coverage provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which address medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically. Clinical UM guidelines are used when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether or not to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the back of the member's card.

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