

Subject:	Level of Care: Specialty Pharmaceuticals	Publish Date:	04/24/2019
Guideline #:	CG-MEDDRUG-8347	Last Review Date:	07/26/2018
Status:	Reviewed		

Description

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

Note: Please see the following related documents for additional information:

- CG-SURG-10 Ambulatory or Outpatient Surgery Center Procedures
- CG-SURG-52 Level of Care: Hospital-Based Ambulatory Surgical Procedures, including Endoscopic Procedures

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 level 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 level of care for the use of an infused pharmacologic or biologic agent is considered **medically necessary** when **all** of the following are present:

1. 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**

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Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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2. 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**
3. 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:
 - a. concerns regarding fluid overload status; **or**
 - b. history of anaphylaxis to prior infusion therapy with a related pharmacologic or biologic agent; **or**
 - c. 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 level 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

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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.

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. *Annals of Hematology* 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. *Journal of Clinical Nursing* 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.
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. *Annals of Oncology*. 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 May 15, 2018.
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.

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3. NCCN Clinical Practice Guidelines in Oncology®. © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on May 16, 2018.
 - Antiemesis (V.2.2018). Revised April 30, 2018.
 - Prevention and Treatment of Cancer-Related Infections. (V.1.2018) Revised December 1, 2017.

Websites for Additional Information

1. National Home Infusion Association. About infusion therapy. Available at: <http://www.nhia.org/about-home-infusion.cfm>. Accessed on. May 15, 2018.

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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
	<u>03/21/2019</u>	<u>Changed the document number from CG-DRUG-47 to CG-MED-83 with same title.</u>
Reviewed	07/26/2018	Medical Policy & Technology Assessment Committee (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.

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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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