Drug and Biologic Coverage Policy

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Coverage Policy Number 1605

Medication Administration Site of Care

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for medication administration site of care point of authorization.

For a list of medications included in medication administration site of care, refer to the **Specialty Care Options and Specialty Care Options Plus - Drug List and Frequently Asked Questions for Health Care Providers** document *[see Related Coverage Resources section]*.

Medical Necessity Criteria

Under many benefit plans, medically necessary services must be rendered in the least intensive setting that is appropriate for the delivery of the services and supplies. Where applicable, the plan may compare the cost-effectiveness of alternative services, settings or supplies when determining least intensive setting.

- An injectable medication must meet applicable medical necessity criteria for coverage. When coverage criteria are met for the injectable medication, this coverage policy is used to determine the medical necessity of the requested site of care.

  For injectable medication medical necessity criteria, please refer to the respective A-Z Index to locate medication's respective coverage policy [see Related Coverage Resources section]

A request initiated from a hospital outpatient setting may be subject to a one-time 30 day approval period to facilitate transition an alternative less intensive site of care if medically necessary.

Alternative less intensive site of care facilities include:

- Non-hospital affiliated outpatient infusion (e.g., ambulatory infusion center or physician office)
- Home infusion

Cigna covers injectable treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite as medically necessary for an individual with ANY of the following:

- The prescribed medication has a site of care restriction for administration per the FDA-approved label
- A documented history of an adverse event warranting a more intense level of care during or following infusion of the prescribed medication unless the adverse event can be appropriately managed by the use of pre-medication(s) or other preventive actions
- A documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or concerns regarding fluid overload status that precludes treatment at an alternative less intensive site of care

  A hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary.

When the above medical necessity criteria for administration of an injectable medication in a hospital outpatient setting, or hospital-affiliated infusion suite are not met, an alternative less intensive site of care should be utilized.

References

1. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.
2. U.S. Food and Drug Administration. Licensed Biological Products with Supporting Documents. U.S. Department of Health & Human Services: http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm.