SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial

DEFINITIONS:
1. Site of Care – the physical location where the infusion therapy is administered (e.g., an inpatient hospital, outpatient hospital-based infusion center, stand-alone infusion center, healthcare provider’s office, or home infusion)
2. Alternative Site of Care – any outpatient infusion site of care outside of an outpatient hospital-based infusion centers (e.g., such as provider’s office or home infusion service providers
3. Approved Site of Care - alternative sites of care or approved hospital-based infusion centers
4. Unapproved Site of Care – any site of care that has been deemed as medically unnecessary, including unapproved hospital based infusion centers that increase the cost of care compared to approved sites of care

POLICY CRITERIA:

COVERED USES:
The Company requires the infusion of certain medications (see Table 1) to be administered at an approved site of care, when an unapproved hospital-based infusion setting is determined to be no longer medically necessary.

CRITERIA:
1. Prior authorization for the medication must be obtained, if necessary. Refer to individual drug specific policies for clinical criteria.
a. For medications that require prior authorization for clinical criteria, the approval or denial of administration in an unapproved hospital outpatient setting is not indicative of approval or denial of the prior authorization for the medication based on clinical criteria.

2. The unapproved hospital-based outpatient infusion center may be considered medically necessary if one of the following criteria is met:
   a. The patient has concomitant conditions or clinical history that may increase the risk of infusion reactions or drug specific adverse events, defined as one of the following:
      i. Recent documented history of severe adverse drug reactions or anaphylaxis to prior treatments of the same or similar therapy.
      ii. Concomitant complex medical conditions that may increase the risk of infusion reactions or complications to therapy. For example, documentation of severe immunosuppression and/or the presence of antibodies that may increase the risk of infusion reactions.
      iii. Use of multiple concurrent therapies of which one or more require infusion services at a higher level of care (e.g., cytotoxic chemotherapy, CAR-T given over same treatment period as requested medication)
      iv. Chronic vascular access complications
      v. Mental health or cognitive changes that require increased level of care for the safe administration of infusions
   b. The unapproved hospital based infusion center is deemed a more appropriate option, as defined by BOTH of the following criteria:
      i. An approved home infusion suite would require an additional 15 miles of travel from the member’s home as compared to unapproved hospital based infusion center in the vicinity. AND
      ii. Home infusion services are not an option because the member’s home is ineligible for infusion services. The eligibility of a member’s home for home infusion can be affected by such factors as:
         1. The location of the member’s home being outside of the infusion provider’s service area, or
         2. Upon inspection, the home infusion provider considers the member’s home to be unfit or unsafe for home infusion services.

3. If criterion 2a or 2b is not met, infusions occurring during the first 60 days of the authorization period may be covered in an unapproved hospital-based infusion center or higher level of care than the approved site of care to allow time for assessment and coordination of an infusion at an approved site of care.
EXCLUSION CRITERIA: N/A

REQUIRED MEDICAL INFORMATION:
For initiation of treatment, a prior authorization form and relevant chart notes documenting medical rationale are required and for continuation of therapy, ongoing documentation of successful response to the medication may be necessary.

AGE RESTRICTIONS:
This policy applies to those members who are 13 years of age and older.

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for up to one (1) year.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
In the outpatient setting, infusion therapy was originally administered at outpatient hospital facilities, but improved technology now allows for safe and effective administration at alternative sites of care; such as medical clinics, stand-alone infusion providers, or home infusion. The practice of providing infusions outside of the hospital setting is well-established and accepted in clinical practice.

Alternative sites of care offer high-quality infusion services for patients and reduce the overall cost of care when compared to unapproved hospital outpatient infusion centers. When more than one medically appropriate site of care is available, PHP will approve the use of the most affordable alternative.

Table 1. The administration of the following medications requires prior authorization for the use of an unapproved hospital-based infusion center when an approved site of care is an available treatment option.
Infusion Therapy Site of Care

POSITION STATEMENT:
In 2010, the National Home Infusion Association (NHIA) published a survey of home infusion providers that showed 829,000 patients were receiving therapy via home infusion. Of these patients, 1.24 million therapies were being administered via home infusion in 2008. Due to an aging population and an increase in chronic conditions requiring higher levels of treatment and monitoring, the U.S. home infusion market has continued to expand and provide clinical and safety data to support its use as a trusted site of care.

Patients receiving therapy via home infusion have been shown to have similar rates of positive clinical outcomes and adverse events as other sites of care. Patients have also reported preference rates of as high as 95% in favor of home infusion sites of care.

A retrospective chart review was done to analyze the incidence and management of infusion reactions to infliximab in an alternative care setting. A total of 796 patients with Crohn’s disease or ulcerative colitis received a combined 5581 infliximab infusions with one home infusion provider between January 2014 and November 2016. Alternative care settings reviewed in the study were identified as either patient’s home or the home infusion provider’s infusion suite. Patients eligible for
alternative care infusion were identified by their physician, and referred to either the home setting or an infusion suite. Use of premedication was determined by the referring physician, and all infusions were administered by a trained nurse following standardized protocols, who also did the post infusion monitoring for a minimum of 60 min following the first 3 infusions and a minimum of 30 min subsequently. In total, 109 infusion reactions (2% of all infusions) were recorded in 62 patients (7.8% of all patients). Of these reactions, 87 (79.8%) were acute, the majority of which were classified as mild (57.5%) or moderate in severity (31.0%). Ten infusions were associated with a severe reaction (11.5%, 0.2% of all infusions), and of these, 8 (9.2%, 0.1% of all infusions) resulted in an emergency room visit. The most common acute reaction was headache (23.0% of all acute IRs), followed by pruritus (14.9%); other common acute reactions included dyspnea (13.8%), flushing (13.8%), chest tightness/discomfort (11.5%), and nausea and/or vomiting (10.3%). In comparison, the REMICADE (infliximab) package insert reported infusion reactions in 18% of infusions, with serious infusion reactions occurring in <1% of patients.

All exceptions to the site of care medical necessity determination will be reviewed on a case-by-case basis.

The infused medication list included in this policy is subject to change.

REFERENCE/RESOURCES: