HAP Specialty Medication Administration-Site of Care Guidelines

DESCRIPTION

FUTURE EFFECTIVE DATE: JUNE 1, 2017

This policy identifies the circumstances when a facility fee will be allowed for specialty medications administered in a hospital outpatient facility.

Alternative sites of care that do not bill with a facility fee (such as non-hospital outpatient infusions, physician offices, ambulatory infusions or home infusions) are well accepted places of service for medication infusion therapy. For drugs that can be self-administered, an outpatient pharmacy can be used for provision of drug therapy.

This policy applies to the following specialty medications* as of June 2017.

Policy applies to the following Specialty Medications*

J0129	Abatacept (Orencia®)
J1602	Golimumab (Simponi Aria®)
J1745	Infliximab (Remicade®)
Q5102	Infliximab, Biosimilar (Inflectra®)
J2505	Pegfilgrastim (Neulasta®)
J3262	Tocilizumab (Actemra®)
*Note	Specialty Medications* that can be safely self-administered (or safely administered in a non-outpatient hospital setting majority of the time) will be continuously evaluated for addition to this policy.

COVERAGE CRITERIA

Review Criteria for Site of Care Selection

1. Outpatient hospital facility-based intravenous medication administration is covered for persons who meet ANY of the following criteria:
    a. Medically unstable based upon submitted clinical history; or
    b. Initial medication infusion or re-initiation after more than 6 months following discontinuation of therapy; or
    c. Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or
    d. Continuing experience of adverse events that cannot be mitigated by pre-medications
2. Outpatient hospital facility-based self-administered medication (e.g. oral, subcutaneous, inhalation) administration is covered for persons who meet ANY of the following criteria:
    a. Patient physically and/or cognitively impaired AND home infusion service or home caregiver not available; or
    b. Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or
    c. Continuing experience of adverse events that cannot be mitigated by pre-medications.

Benefit Considerations:

1. This policy applies to HAP Commercial, AHL/PPO and QHP members greater than age of 18 years.
2. Medications included in this policy that have existing medication clinical use policies MUST meet medication prior authorization criteria for coverage.

3. Specialty medication administration should occur at a HAP/AHL Affiliated or Contracted facility by a HAP/AHL Affiliated or Contracted provider.

Supporting Information and Clinical Evidence Background:

Home setting infusion therapy is well established and accepted by physicians as evidenced by the 2010 National Home Infusion Association survey reported approximately 829,000 patients received 1.24 million home infusion therapies in 2010. Of which, 129,071 infusion therapies were specialty medications.[1]

A systematic review, which included 13 relevant studies identified through MEDLINE, EMBASE and Science Citation Index search, concluded that patients receiving home infusions were no more likely to experience adverse drug event or side effects, and patients overwhelmingly preferred receiving infusion at home rather than in health care facilities. Furthermore, it was suggested that home infusion is well suited to medication delivery in many other clinical areas, including neurology, oncology, hematology, rheumatology, and gastroenterology.[2]

The 2016 MCG™ Care Guidelines on Home Infusion Therapy reports on patient criteria suitable for home infusion therapy as an alternative to physician office or ambulatory infusion facility. This guideline reports on patient characteristics who do not require a close observation with reliable venous access and clinical stability for safe home infusion therapy. [3]

Additionally, the American Academy of Allergy Asthma and Immunology has published guidelines for suitability of patients to receive treatments in various care setting including clinical characteristics which home infusion may or may not be suitable. [4]

Medication Specific Studies for Safety

Infusion-related adverse reactions: Infliximab

The expected rates of infusion reactions are lower in the subsequent infliximab infusions compared to the first dose. The 5 year follow up of TREAT registry patients in the infliximab-treated group (n=3420 receiving 53,000 infusions), 3% of infliximab infusions were associated with an infusion related reaction, of which, less than 1% of reactions were considered to be serious. This is much lower rate than 18-20% of infusion reaction reported with infliximab first dose therapy. [5] In this study, 53% were pretreated with acetaminophen, 56% with antihistamines and 14% took prednisone to minimize the risk for infusion related reactions. The most common infusion related reactions reported were headaches and arthritis which were considered mild to moderate in severity. [6]

A chart review of 3161 patients who received a combined 20,976 infliximab infusions in community clinics was conducted to evaluate safety across all types of patients. This study found severe infusion reactions or severe adverse events to be rare. A total of 524 (2.5% of all infusions) adverse events were noted of which, 50% were mild reactions and 44% were considered moderate reactions. None of the reactions observed required hospital admissions. The authors concluded that infliximab infusions are safe in community setting. [7]

Infusion-related adverse reactions: abatacept, golimumab and tocilizumab

In a controlled phase trial with 24 weeks follow up, 1.1% of golimumab infusions were associated with an infusion reaction compared with 0.2% of infusions in the control group. The most common infusion reaction in golimumab treated patients was rash and no serious infusion reactions were reported. [8] In the 24 week, controlled clinical studies, tocilizumab infusion related adverse events were 7-8% while the placebo group reported 5%. Headache (1%) and skin reactions (1%) including rash, pruritus and urticarial were the most frequently reported infusion related side effect, which did not lead to any treatment discontinuation. [9] Infusion-related events were more common in the abatacept treated patients than the placebo patients; 9% and 6% for respectively. The most frequently reported events (1%-2%) were dizziness, headache, and hypertension. [10]

Hypersensitivity: infliximab, abatacept, golimumab and tocilizumab

Hypersensitivity (true allergy) to infliximab, abatacept, golimumab and toclizumab are considered rare with incidence

of 0.1 to 0.3% observed with the first dose. [5, 8, 9, 10] There is one case report of a possible delayed hypersensitivity to infliximab occurred in Europe. [11] There are no reports published to date with abatacept, golimumab and toclizumab for delayed hypersensitivity or hypersensitivity observed outside of first dose.

Safety of home infusion therapy:

A study of ten children receiving infliximab infusions administered at home reported no severe adverse events (palpitations, blood pressure instability, hyperemia, respiratory symptoms) that occurred during home infusions. Three patients experienced difficulty with IV access requiring multiple attempts, but all were able to receive their infusions. Enrolled children had the following criteria: a minimum of three or more in-patient infliximab infusions without adverse events, clinical remission at the time of entry into home infusion program, good compliance with maintenance medications and insurance approval for home care nurses to administer infusions. This study demonstrated that in this select patients, infliximab home infusions were safe, patients and families preferred home infusions since time missed from school and work were reduced. [12]

Pegfilgrastim (Neulasta) On-body Injector (Onpro®)

An open-label, multicenter, randomized, phase 1 study compared safety and pharmacokinetics of pegfilgrastim On-body injector drug delivery with manual injection. The study included 267 subjects randomized to receive a single 6-mg subcutaneous dose of pegfilgrastim from an on-body injector (n = 137) or manually from a prefilled syringe (n = 130). The study found that adverse events related to device were higher with the injector group (13.4%) than observed in the pre-filled syringes manual administration group (3.9%). Contact dermatitis (3.0 %), medical device-site reaction (2.2 %), and headaches (2.2 %) were the most common injector-related adverse events found at higher rates compared to manual pre-filled syringes administration. One subject in the on-body injector group was excluded due to partial delivery of the drug. Additionally, eleven percent of subjects reported injector removal was difficult and 24% of subjects required using an adhesive remover to detach the device. [13]

Partial drug delivery, drug leakage, and device errors are of concern with On-body injector. A phase 1 study completed on 150 healthy subjects provided 297 drug deliveries reported red light indicator activation indicating device error (n=2) and drug leakage/partial delivery (n=3). [14] Another study evaluated implementation of pegfilgrastim on-body injector on 41 oncology patients provided 104 pegfilgrastim treatments through on-body injector. This study method included extensive patient education for on-body injector safe and proper drug delivery as well as key points to monitor for any failures or partial drug deliveries. The results showed that out of 104 treatments, there was 1 delivery failure, 3 leakages, 1 loosened device and 1 skin irritation. The subjects who experienced delivery failure and drug leakages were treated with manual injection in clinic the next day. [15]

The initial clinical trials for pegfilgrastim as well as the pharmacokinetic study have been conducted using the pre-filled syringes manual injections. [13, 16] These trials represent total of 1566 patients undergone clinical trials utilizing pegfilgrastim prefill syringes via subcutaneous injections. Furthermore, the prescribing information for pegfilgrastim (Neulasta) includes patient education on self-injection technique for prefilled syringes given subcutaneously. [16]

References:

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This Benefit policy discusses the medical criteria for covered services. Coverage of services for Members is based on the Member's coverage contract. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Advantage Members).
Please note: Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.

COVERAGE

HAP HMO	**Yes** - Must meet Criteria
HAP POS	**Yes** - Must meet Criteria
AHL PLANS	**Yes** - Must meet Criteria
QHP PLANS	**Yes** - Must meet Criteria
MEDICARE ADVANTAGE	No

RELATED POLICY(IES)

1. **ANTI-INFLAMMATORY BIOLOGICS FOR THE TREATMENT OF RHEUMATOID CONDITIONS: ETANERCEPT (ENBREL®), ADALIMUMAB (HUMIRA®), INFLIXIMAB (REMICADE®), CERTOLIZUMAB PEGOL (CIMZIA®), GOLIMUMAB (SIMPONI®), ABATACEPT (ORENCIA®), RITUXIMAB (RITUXAN®), TOCILIZUMAB (ACTEMRA®), ANAKINRA (KINERET®), USTEKINUMAB (STELARA®)**
2. **BIOLOGIC DRUG MANAGEMENT of INFLAMMATORY BOWEL DISEASE: ULCERATIVE COLITIS and CROHN'S DISEASE**

3. **DRUG THERAPY for the TREATMENT of MODERATE-to-SEVERE PLAQUE PSORIASIS**

EFFECTIVE DATE

06/01/2017

REVISED DATE

02/23/2017

REVIEWED DATE

02/27/2017