

ASSISTED ADMINISTRATION OF CLOTTING FACTORS AND COAGULANT BLOOD PRODUCTS

Policy Number: PHARMACY 266.17 T2

Effective Date: January 1, 2019

Table of Contents	Page
INSTRUCTIONS FOR USE	1
CONDITIONS OF COVERAGE	1
BENEFIT CONSIDERATIONS	2
COVERAGE RATIONALE	2
DEFINITIONS	3
APPLICABLE CODES	4
POLICY HISTORY/REVISION INFORMATION	5

Related Policies
<ul style="list-style-type: none"> • Clotting Factors and Coagulant Blood Products • Drug Coverage Guidelines • Eloctate™ (Antihemophilic Factor (Recombinant), FC Fusion Protein) for Connecticut Lines of Business • Home Health Care • Private Duty Nursing Services (PDN)

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership for New Jersey large and small group and New York lines of business. ²
Benefit Type	Medical ^{3,4} Pharmacy ⁴
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ¹
Precertification with Medical Director Review Required	Yes ¹
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Home

Special Considerations

¹Precertification through Oxford's Medical Management by a Medical Director or their designee is required for the assisted administration of clotting factor drugs, **and** for self-administered clotting factor drugs provided by a Hemophilia Treatment Center under the medical benefit. All other self-administered clotting factor drugs have coverage under the pharmacy benefit and may require precertification.

²For coverage of clotting factor drugs for New Jersey large and small groups, and New York lines of business including Eloctate, refer to the policy titled [Clotting Factors and Coagulant Blood Products](#).

For coverage of clotting factor drugs including Eloctate and/or assisted administration of these drugs for Connecticut lines of business refer to the policies titled [Drug Coverage Guidelines, Eloctate™ \(Antihemophilic Factor \(Recombinant\), FC Fusion Protein\) for Connecticut Lines of Business](#) and [Home Health Care](#).

³Assisted administration of clotting factor drugs is covered under the medical benefit.

⁴Self-administered clotting factor drugs are covered in network only under the pharmacy benefit except for self-administered clotting factors provided by a Hemophilia Treatment Center which are covered under the medical benefit and require precertification.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Assisted administration of clotting factor drugs is covered under the medical benefit. For New York lines of business, coverage is in-network only.

Self-administration of clotting factor drugs is covered in network only under the pharmacy benefit except for:

- Self-administration of clotting factor drugs provided by a Hemophilia Treatment Center which is covered under the medical benefit.

Clotting factors may be a covered service under the medical or pharmacy benefit. Please refer to the member specific benefit plan document (certificate of coverage/riders) for additional information.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Non-Emergent Home Health Care - Assisted Administration of Factor

Oxford will cover medically necessary and appropriate assisted administration of clotting factor drugs for the bleeding episodes associated with hemophilia, including the purchase of blood products and blood infusion equipment, when provided by a home care provider certified or licensed by the appropriate state agency.

For New York lines of business, in addition to the Home Health Care Benefits available under the member specific benefit plan document (Certificate of Coverage), Oxford will cover non-emergent administration of Hemophilia Factor in the home when provided by a Participating Home Health Agency, certified or licensed by the appropriate state agency. This additional Home Health Care benefit covers both the Factor and the administration services when

assisted administration is medically necessary. Coverage will be provided in lieu of receiving medically necessary covered assisted-administration service from a Physician or another health practitioner in an office or out-patient setting.

Requirements for Assisted Administration of Clotting Factor Drugs

- It must be delivered or supervised by licensed professional medical personnel in order to obtain the specified medical outcome, and provide for the safety of the patient.
- It is ordered by a Physician, Nurse Practitioner or Physician Assistant overseeing the treatment of hemophilia care.

Additional Information

- Administration of clotting factor drugs may be subject to visit limitations. Please check the member specific benefit plan document (certificate of coverage and/or summary of benefits) for the home infusion services benefit.
- Medical supplies and medications that are used in conjunction with a home health care visit are covered as part of that visit. Some examples are, but not limited to, surgical dressing, catheters, syringes, irrigation devices.
- Reimbursement for home health care visits and supplies are contractually determined.
- Laboratory services should be referred to a contracted vendor or otherwise covered per the member specific benefit plan document.

Home Health Care Coverage Limitations and Exclusions

- Oxford will determine if benefits are available by reviewing both the skilled nature of the service and the need for Physician-directed medical management. A service will not be determined to be "skilled" simply because there is not an available caregiver.
- Covered pharmaceuticals, drugs, and DME provided in connection with home health services may be subject to separate benefit categories, please reference the member specific benefit plan document (certificate of coverage and/or summary of benefits).
- Private Duty Nursing (there may be a specific benefit related to the Member's benefit package. Refer to the member specific benefit plan document as well as the policy titled [Private Duty Nursing Services \(PDN\)](#) policy for additional information.
- Home Health Services beyond benefit limits, e.g., visits.
- Cost of a nurse to open a case, unless skilled nursing care is needed at the time of the visit.
- Services furnished to family members other than the member.
- Comfort or convenience items.

DEFINITIONS

Home Health Agency: A program or organization authorized by law to provide health care services in the home.

Home Health Visit: Each visit by a member of a home care team shall be considered as one home health care visit.

Note: Each visit by a home health aide, nurse, or other recognized provider whose services are authorized under the home health care plan up to four hours is considered one visit.

Intermittent - Part-Time Home Health Services (CMS): Where a patient is eligible for coverage of home health services, Medicare covers either part-time or intermittent home health aide services or skilled nursing services subject to the limits below. The law at §1861(m) of the Act clarified: "the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours each week).

Extensions are for exceptional circumstances when the need for additional care is finite and predictable.

Intermittent Visit(s) (CMS): "Intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

Place of Residence: Wherever the patient makes his/her home. This may be his/her dwelling, an apartment, a relative's home, home for the aged, a custodial care facility, or some other type of institution.

Skilled Care (CMS): Skilled nursing and/or skilled rehabilitation services are those services, furnished pursuant to physician orders, that:

- Require the skills of qualified technical or professional health personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech-language pathologists or audiologists; and

- Must be provided directly by or under the general supervision of these skilled nursing or skilled rehabilitation personnel to assure the safety of the patient and to achieve the medically desired result.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Home infusion/specialty drug administration, per visit each additional hour (list separately in addition to primary procedure)

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
J7170	Injection, emicizumab-kxwh, 0.5 mg
J7175	Injection, factor x, (human), 1 i.u.
J7177	Injection, human fibrinogen concentrate (Fibryga), 1 mg
J7178	Injection, human fibrinogen concentrate, not otherwise specified, 1 mg
J7179	Injection, von willebrand factor (recombinant), (vonvendi), 1 i.u. vwf:rc0
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU
J7181	Injection, factor XIII A-subunit, (recombinant), per IU (Tretten)
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (Novoeight), per IU
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF:RC0
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (XYNTHA), per IU
J7186	Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u.
J7187	Injection, von Willebrand factor complex (Humate-P), per IU VWF:RCO
J7188	Injection, Factor VIII (antihemophilic factor, recombinant), per IU
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 mcg
J7190	Factor VIII (antihemophilic factor, human) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified
J7193	Factor IX (antihemophilic factor, purified, nonrecombinant) per IU
J7194	Factor IX complex, per IU
J7195	Injection, factor IX (antihemophilic factor, recombinant) per IU, not otherwise specified
J7198	Antiinhibitor, per IU
J7199	Hemophilia clotting factor, not otherwise classified
J7200	Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU
J7201	Injection, factor IX, Fc fusion protein, (recombinant), Alprolix, 1 IU
J7202	Injection, factor ix, albumin fusion protein, (recombinant), Idelvion, 1 i.u.
J7205	Injection, Factor VIII Fc fusion protein (recombinant), per IU
J7207	Injection, factor VIII, (antihemophilic factor, recombinant), pegylated, 1 i.u.
J7209	Injection, factor VIII, (antihemophilic factor, recombinant), (Nuwiq), 1 i.u.
J7210	Injection, factor VIII, (antihemophilic factor, recombinant), (Afstyla), 1 i.u.
J7211	Injection, factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 i.u.
S9345*	Home infusion therapy, anti-hemophilic agent infusion therapy (e.g., factor VIII); administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

***Coding Clarification:** HCPCS Code S9345 should only be billed with CPT Code 99601.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none">• Updated list of applicable HCPCS codes to reflect annual code edits:<ul style="list-style-type: none">○ Added J7170 and J7177○ Removed Q9995○ Revised description for J7178• Archived previous policy version PHARMACY 266.16 T2