

Department of Origin: Pharmacy	Effective Date: 2/22/2022
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date Approved: 2/16/2022
Pharmacy Clinical Policy Document: Site of Care for Provider-Administered Medications	Replaces Effective Clinical Policy Dated: 02/18/21
Reference #: PC/S009	Page: 1 of 3

PURPOSE:

The intent of the Site of Care for Provider Administered Medications Pharmacy Clinical Policy is to provide coverage guidelines for the *medically necessary* and most cost-effective site of care for provider-administered drugs, infusions and injectable therapies.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

The Plan covers provider-administered drugs, infusions, injectable therapies, and associated services at the most cost-effective site of care. Requests for select drugs and associated health care services that are not *medically necessary* for administration in a hospital-based outpatient setting are excluded from coverage.

GUIDELINES:

Provider-administered drugs, infusions or injectable therapy must be delivered at a physician's office, infusion center [including pharmacy infusion center] or home setting unless *medical necessity* for a hospital-based site of care is met, and supported by clinical documentation – Must satisfy any of the following: I - VI

- I. The requested therapy is subject to limited distribution and is not available for administration at a non-hospital site of care; or
- II. The member is less than 18 years of age; or
- III. One dose may be approved at a hospital-based site of care, to allow for adequate transition time and prevent a delay in care, for any of the following: A or B
 - A. Request is for an initial dose of a newly prescribed therapy, including, but not limited to, a new immune globulin product, changing from a *reference* product to a *biosimilar*, changing from a *biosimilar* product to a *reference* product, reinitiating therapy after not having received it for equal to or greater than six months; or
 - B. Request is for an initial review for continuation of therapy.
- IV. There is potential risk to the member's clinical status which would require immediate access to specific services of a hospital setting, including access to emergency resuscitation equipment and personnel, inpatient admission/intensive care may be necessary – as evidenced by documentation of any of the following: A - C
 - A. The member has experienced a severe or life-threatening reaction with previous infusion/injection of the same or similar product, despite appropriate premedication; or

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B. The member is medically unstable for administration of therapy at a non-hospital site of care due to an inability to safely tolerate intravenous volume fluid loads, including impaired/unstable cardiac or renal function; or

C. Unstable vascular access.

V. Alternate settings are inappropriate due to both of the following: A and B

A. Home infusion services are deemed unsafe, as documented by the ordering provider, social worker, or infusion provider; and

B. The nearest office-based provider or infusion center [including pharmacy infusion center] capable of providing the service is 60 miles driving distance or greater from the member's home.

VI. The requested hospital-based infusion center is the least costly site of care option - reviewed on a case-by-case basis.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:

Biosimilar:

A biological product that has been demonstrated by the US Food and Drug Administration (FDA) to be similar to the reference product in its intended use and potential adverse effects. From a policy and benefit perspective, biosimilars are not the same as generics.

Medical Necessity:

Any health care services, preventive health care services, and other preventive services that PCHP, PIC, or Plan Administrator, in its discretion and on a case-by-case basis, determines are appropriate and necessary in terms of type, frequency, level, setting, and duration, for the diagnosis or condition; and the care must:

1. Be consistent with the medical standards and generally accepted practice parameters of providers in the same or similar general specialty as typically manages the condition procedure or treatment at issue; and
2. Help restore or maintain the member's health; or
3. Prevent deterioration of the member's condition; or
4. Prevent the reasonably likely onset of a health problem or detect an incipient problem.

Reference product:

The single biological product licensed by the US FDA under section 351(a) of the PHS Act, against which a proposed biosimilar biological product is evaluated in its biosimilar application.

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Prior Authorization: Yes, per network provider agreement.

List of Drugs impacted by Site of Care

[Site of Care List.pdf](#)

CODING:

CMS place of service codes

- 01 Pharmacy – A facility or location where drugs and other medically related items and services are sold, dispensed, or otherwise provided directly to patients
- 11 Office – Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
- 12 Home – Location, other than a hospital or other facility, where the patient receives care in a private residence
- 19 Off Campus-Outpatient Hospital - A portion of an off-campus hospital provider department which provided diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
- 22 On Campus-Outpatient Hospital – A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines

DOCUMENT HISTORY:

Created Date: 01/21/21 (previously MC/K003)
Reviewed Date: 01/20/22
Revised Date:

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျဉ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

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If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိန်အယိ, နမူနာ ကျိန်အတိအကျတို့ တလက်တလက်စွာ နှိပ်စက်သွန်သိုလိမ့်။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

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