



MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 03/01/18
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 01/22/19
ARCHIVE DATE:

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS (cont.)

Description:

Infusion therapy can be given in the hospital and in outpatient settings as alternative sites of service. Infusions can be given intravenously (IV) or subcutaneously (SC). Subcutaneous administration can be given via infusion pump or via syringe and butterfly needle (rapid push).

Review for medical necessity of select IV, SC and injectable therapy services will include determination of the medical necessity of the appropriate site of service.

Preferred sites of service non-hospital outpatient facility-alternative sites of service include:

- Physician's office
- Infusion center
- Home

Non-preferred sites of service include:

- Hospital outpatient facility and hospital-owned or operated office and infusion centers
- Urgent Care Centers

Non-hospital sites of service are the **preferred sites of service** for medications addressed in this Medical Coverage Guideline.

Criteria:

COVERAGE IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

Non-hospital sites of service are the **preferred sites of service** for medications addressed in this Medical Coverage Guideline.

- Medications administered in a **non-hospital site of service (preferred setting)** may be **eligible for coverage** with documentation of **ALL** of the following:
 1. Member has the medication benefit with BCBSAZ
 2. BCBSAZ review has determined the medication is **medically necessary**. Medical necessity is determined by applying criteria found in a separate Medical Coverage Guideline (MCG). If a separate MCG does not exist for the medication, BCBSAZ will review the request to determine if the medication has been approved by the Food and Drug Administration (FDA) for that specific indication.



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SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS (cont.)

Criteria: (cont.)

- Medications administered in a **hospital outpatient setting (non-preferred setting)** may be **eligible for coverage** with documentation of **ALL** of the following:
 1. Member has the medication benefit with BCBSAZ
 2. BCBSAZ review has determined the medication is **medically necessary**. Medical necessity is determined by applying criteria found in a separate Medical Coverage Guideline (MCG). If a separate MCG does not exist for the medication, BCBSAZ will review the request to determine if the medication has been approved by the Food and Drug Administration (FDA) for that specific indication.
 3. Facility is not an urgent care center
 4. **ONE** of the following:
 - Individual's home is not eligible for home infusion services (such as the home is not within the service area or the home is deemed unsuitable for care by the home infusion provider) **AND** all non-hospital outpatient settings/ alternative sites of service are greater than 15 miles from individual's home in metropolitan area **OR** greater than 30 miles from individual's home in rural area
 - Individual's medical condition(s) requires a higher level of care than preferred sites of service can provide for the infusion therapy due to **ANY** of the following identified medical risks or co-morbidity(s) including:
 - a. Known history of severe adverse drug reactions and/or anaphylaxis to prior treatment with a related or similar drug
 - b. Cytokine release syndrome (CRS)
 - c. Known cardiac or pulmonary conditions that increase the risk of an adverse reaction
 - d. Unstable renal function which decreases the ability to respond to fluids
 - e. Difficult or unstable vascular access
 - f. Cognitive conditions or mental status changes that impact the safety of infusion therapy
 - g. Documented, based on individual's medical condition, as not medically appropriate for non-hospital outpatient setting alternative site of service (**preferred setting**)
 - h. **Note: Site of service requirements may be waived for the first dose to determine that drug is well tolerated**
- Medications that do not meet site of service criteria are considered **not medically necessary**.



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Criteria: (cont.)

Blue Cross Blue Shield of Arizona (BCBSAZ) determines what medications require medical necessity for site of service. The medication list may change at any time without notice. Some large (100+) groups may customize certain benefits, including adding or deleting requirements.

Medication	Brand Name(s)	HCPCS / CPT Code	Separate MCG
abatacept (IV)	Orencia®	J0129	O513
agalsidase beta	Fabrazyme®	J0180	O649
alglucosidase alfa (IV)	Lumizyme®	J0221	
alpha1-proteinase inhibitors	Aralast® NP Glassia® Prolastin®-C Zemaira®	J0256 J0257	O1001
belimumab IV	Benlysta®	J0490	O979
C1 esterase inhibitor, human	Beriner®	J0597	O829
denosumab	Prolia®	J0897	O594
eculizumab	Soliris®	J1300	O938
elosulfase alfa	Vimizim™	J1322	O913
golimumab	Simponi Aria®	J1602	O566
idursulfase	Elaprase®	J1743	O991
imiglucerase	Cerezyme®	J1786	O1003
immune globulin (IV)	Bivigam™ Carimune NF® Flebogamma DIF® Gammagard Liquid® Gammagard S/D® Gammaked® (IV) Gammaplex® Gamunex-C® Octagam® Privigen®	J1459 J1556 J1557 J1561 J1566 J1568 J1569 J1572 J1575 J1599 90283 90399	O18
immune globulin (SC)	Cuvitru® Gammagard Liquid Gamunex-C Gammaked Hizentra® HyQvia®	C9399 J1555 J1559 J1561 J1569 J1575 J3590 90284	O18
infliximab	Remicade®	J1745	O198
infliximab-dyyb	Inflectra®	Q5102 Q5103	O993
infliximab-abda	Renflexis®	Q5102 Q5104	O993



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Criteria: (cont.)

Medication	Brand Name(s)	HCPCS / CPT Code	Separate MCG
rituximab	Rituxan® (non-oncologic)	J9310	O947
rituximab and hyaluronidase, human (SC)	Rituxan Hycela (non-oncologic)	C9399 J9999	O525
tocilizumab	Actemra®	J3262	O628
vedolizumab	Entyvio®	C9399 J3380 J3590	O912
velaglucerase alfa	Vpriv®	J3385	O1003

Refer To:

- BCBSAZ Medical Coverage Guideline(s) specific to requested medication

Resources:

Literature reviewed 09/04/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. Blue Cross Blue Shield of Arizona. Benefit Plan Booklet.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator 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, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

