BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE:**	**12/07/21**
SECTION: ADMINISTRATIVE SPECIALTY MEDICATIONS	**LAST REVIEW DATE:**	**11/16/23**
	CURRENT EFFECTIVE DATE:	**10/14/24**
	LAST CRITERIA REVISION DATE:	**08/15/24**
NEXT ANNUAL REVIEW DATE: 4TH QTR 2024	**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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 12/07/21**
SECTION: ADMINISTRATIVE SPECIALTY MEDICATIONS	**LAST REVIEW DATE: 11/16/23**
	CURRENT EFFECTIVE DATE: 10/14/24
	LAST CRITERIA REVISION DATE: 08/15/24
NEXT ANNUAL REVIEW DATE: 4TH QTR 2024	**ARCHIVE DATE:**

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Description:

This Evidence-Based Criteria applies to certain medications that require healthcare provider administration in an outpatient setting.
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.
Non-hospital sites of service are the **preferred sites of service.**

Preferred sites of service non-hospital outpatient facility include:
- Non-Hospital affiliated Freestanding Infusion Center
- Home

Non-preferred sites of service include:
- Hospital outpatient facility
- Hospital-owned, operated, or affiliated physician offices and infusion centers
- Urgent Care Centers

Criteria:

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

Preferred Setting: Freestanding infusion center and Home

- Medications administered in a **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 separate Evidence-Based Criteria. If separate Evidence-Based Criteria 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

Non-Preferred Setting: Hospital outpatient facility, hospital-owned, operated, or affiliated physician offices and infusion centers, and urgent care centers

- Medications administered in a **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 separate Evidence-Based Criteria. If separate Evidence-

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Based Criteria 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) **as defined by either:** All Preferred sites of service are:

     a. Greater than 15 miles from individual's home in a **metropolitan area** **AND** there are no preferred sites of service located closer to the patients' home than the requested non-preferred site of service **OR**
     b. Greater than 40 miles from individual's home in a **rural area** **AND** there are no preferred sites of service located closer to the patients' home than the requested non-preferred site of service.

   - 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 (Note: this is for initiation of a medication and does not apply for continuation if the individual is tolerating a medication)
     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)**

- In certain circumstances, site of service requirements may be waived for the first dose

- Medications that do not meet site of service criteria are considered ***not medically necessary***

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE SPECIALTY MEDICATIONS

NEXT ANNUAL REVIEW DATE: 4TH QTR 2024

ORIGINAL EFFECTIVE DATE: 12/07/21
LAST REVIEW DATE: 11/16/23
CURRENT EFFECTIVE DATE: 10/14/24
LAST CRITERIA REVISION DATE: 08/15/24
ARCHIVE DATE:

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

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. Site of service requirements may be waived for combination oncologic therapeutic regimens when combination therapy requires higher level of care.

Medication	Code(s)	Date added to SOS
Actemra® (tocilizumab)	J3262	06/19/2019
Adakveo® (crizanlizumab-tmca)	J0791	02/16/2023
Adcetris® (brentuximab vedotin)	J9042	02/16/2023
Adzynma (apadamtase alfa)	C9167, J3590	05/16/2024
Aldurazyme® (leronidase)	J1931	12/01/2022
Alimta® (pemetrexed)	J9305	08/04/2020
Alyglo (immune globulin (human)-stwk)	J1599	05/16/2024
Amondys 45 (casimersen)	J1426	05/16/2024
Amvuttra® (vutrisiran)	J0225	02/16/2023
Apretude (cabotegravir)	J0739	02/16/2023
Aralast® NP (alpha1-proteinase inhibitors)	J0256	06/18/2019
Asceniv™ (immune globulin)	J1554	08/04/2020
Avsola™ (infliximab-axxq)	Q5121	12/07/2021
Bavencio® (avelumab)	J9023	02/16/2023
Benlysta® (belimumab) IV	J0490	06/18/2019
Berinert® (C1 esterase inhibitor, human)	J0597	06/18/2019
Bivigam™ (immune globulin, human)	J1556	06/18/2019
Bortezomib (Dr. Reddy's, Fresenius kabi, Hospira)	J9046, J9048, J9049	5/18/2023
Briumvi™ (ublituximab-xiiy)	J2329	02/16/2023
Cabenuva (cabotegravir-rilpivirine)	J0741	12/07/2021
Cablivi® (caplacizumab-yhdp)	C9047, J3590	03/31/2020
Cerezyme® (imiglucerase)	J1786	06/18/2019
Cinqair® (reslizumab)	J2786	02/16/2023
Cinryze® (C1 esterase inhibitor, human)	J0598	12/07/2021
Cipla (Lanreotide Acetate)	J1930, J1932	05/18/2023
Crysvita® (burosumab)	J0584	02/16/2023
Cutaquig® (immune globulin, human-hipp)	J1551	08/04/2020
Cuvitru® (immune globulin, human)	J1555	06/18/2019
Darzalex® (daratumumab)	J9145	12/01/2022
Darzalex Faspro® (daratumumab abd hyaluronidase-fihj)	J9144	02/16/2023
Elaprase® (idursulfase)	J1743	06/18/2019
Elelyso™ (taliglucerase)	J3060	02/16/2023
Elfabrio® (pegunigalsidase alfa-iwxj)	J2508	11/16/2023
Elevidys (delandistrogene moxeparvovec-rokl)	J1413	02/15/2024
Enhertu® (fam-traztuzumab deruxtegan-nxki)	J9358	07/19/2022
Enjaymo™ (sutimlimab-jome)	J1302	12/01/2022
Entyvio® (vedolizumab)	J3380	06/18/2019
Evenity™ (romosozumab-aqqg)	J3111	03/31/2020
Evkeeza® (evinacumab-dgnb)	J1305	02/16/2023

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Exondys 51 (eteplirsen)	J1428	05/16/2024
Fabrazyme® (agalsidase beta)	J0180	06/18/2019
Fasenra® (benralizumab)	J0517	02/16/2023
Flebogamma DIF® (immune globulin, human)	J1572	06/18/2019
GamaSTAN® (immune globulin)	J1560	12/01/2022
GamaSTAN SD® (immune globulin)	J1460	12/01/2022
Gamifant® (emapalumab-lzsg)	J9210	02/16/2023
Gammagard Liquid® (immune globulin, human)	J1569	06/18/2019
Gammagard S/D® /Carimune NF (immune globulin, human)	J1566	06/18/2019
Gammaplex® (immune globulin, human)	J1557	06/18/2019
Gamunex-C®/Gammaked® (immune globulin, human)	J1561	06/18/2019
Givlaari® (givosiran)	J0223	02/16/2023
Glassia® (alpha1-proteinase inhibitors)	J0257	06/18/2019
Haegarda® (C1 esterase inhibitor, human)	J0599	03/31/2020
Hizentra® (immune globulin, human)	J1559	06/18/2019
HyQvia® (immune globulin, human, with recombinant human hyaluronidase)	J1575	06/18/2019
Ilaris® (canakinumab)	J0638	02/16/2023
Ilumya® (tildrakizumab-asmn)	J3245	02/16/2023
Imfinzi® (durvalumab)	J9173	08/04/2020
Immune globulin, (human), IM	90281	12/01/2022
Immune globulin (human), IV	90283	08/04/2020
Immune globulin (human), SC	90284	08/04/2020
Immune Globulin, Unlisted	90399	08/04/2020
Inflectra® (infliximab-dyyb)	Q5103	06/18/2019
Jemperli (dostarlimab-gxly)	J9272	02/16/2023
Kadcyla® (ado-trastuzumab emtansine)	J9354	07/19/2022
Kanuma® (sebelipase alfa)	J2840	12/01/2022
Keytruda® (pembrolizumab)	J9271	08/04/2020
Kimmtrak® (tebentafusp-tebn)	C9095, J9274	12/01/2022
Kisunla™ (donanemab-azbt)	J0175	08/15/2024
Krystexxa® (pegloticase)	J2507	12/07/2021
Kyprolis® (carfilzomib)	J9047	02/16/2023
Lamzede® (velmanase alfa)	J0217	02/15/2024
Lemtrada® (alemtuzumab)	J0202	05/26/2020
Leqembi® (lecanemab)	J0174	08/17/2023
Leqvio® (inclisiran)	J1306	02/16/2023
Libtayo® (cemiplimab-rwic)	J9119	02/16/2023
Lumizyme® (alglucosidase alfa)	J0221	06/18/2019
Lunsumio™ (mosunetuzumab-axgb)	J9350	05/18/2023
Mepsevii® (vestronidase alfa-vjbk)	J3397	12/01/2022
Monjuvi® (tafasitamab-cxix)	J9349	12/07/2021
Naglazyme® (galsulfase)	J1458	12/01/2022
Nexviazyme® (avalglucosidase alfa-ngpt)	J0219	12/01/2022
Nucala (mepolizumab)	J2182	07/19/2022
Nulibry® (fosdenopterin hydrobromide)	C9399, J3490	02/16/2023
Ocrevus® (ocrelizumab)	J2350	03/31/2020
Octagam® (immune globulin, human)	J1568	06/18/2019
Omvoh (mirikizumab-mrkz)	C9168, J3590	11/16/2023
Onpattro® (patisiran)	J0222	03/31/2020

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Opdivo® (nivolumab)	J9299	02/16/2023
Opdualag™ (nivolumab-relatimab)	J9298	02/16/2023
Orencia® (abatacept) IV	J0129	06/18/2019
Oxlumo® (lumasiran)	J0224	02/16/2023
Panzyga® (immune globulin, human-ifas)	J1576	08/04/2020
Pemetrexed (Bluepoint)	J9322	08/17/2023
Pemetrexed (Hospira)	J9323	08/17/2023
Pemetrexed (Sandoz)	J9321	08/17/2023
Pemfexy® (pemetrexed)	J9304	12/01/2022
Perjeta® (pertuzumab)	J9306	12/07/2021
Phesgo® (pertuzumab/trastuzumab/hyaluronidase)	J9316	02/16/2023
PiaSky™ (crovalimab-akkz)	J3590	08/15/2024
Pombiliti (Palifermin)	J1203	11/16/2023
Privigen® (immune globulin, human)	J1459	06/18/2019
Prolastin®-C (alpha1-proteinase inhibitors)	J0256	06/18/2019
Prolia® (denosumab)	J0897	06/18/2019
Radicava® (edaravone)	J1301	02/16/2023
Reblozyl® (luspatercept-aamt)	J0896	08/17/2023
Remicade® (infliximab)	J1745	06/18/2019
Renflexis® (infliximab-abda)	Q5104	06/18/2019
Revcovi® (elapeg ademase-lvlr)	C9399, J3590	02/16/2023
Riabni™ (rituximab-arrs)	Q5123	12/07/2021
Rituxan® (rituximab) non-oncologic	J9312	06/18/2019
Rituxan Hycela® (rituximab and hyaluronidase, human), non-oncologic	J9311	06/18/2019
Ruconest® (C1 esterase inhibitor, human)	J0596	12/01/2022
Ruxience™ (rituximab-pvvr)	Q5119	08/04/2020
Ryplazim® (plasminogen, human-tvmh)	J2998	12/01/2022
Rystiggo® (rozanolixizumab-noli)	J3590	08/17/2023
Sandostatin® LAR Depot (octreotide acetate)	J2353	02/16/2023
Saphnelo™ (nifrolumab-fnia)	J0491	12/07/2021
Signifor® LAR (pasireotide)	J2502	02/16/2023
Simponi Aria® (golimumab)	J1602	06/18/2019
Skyrizi® (risankizumab-rzaa) IV	J2327	02/16/2023
Soliris® (eculizumab)	J1300	06/18/2019
Somatuline® Depot (lanreotide)	J1930	02/16/2023
Spevigo® (spesolimab)	J1747	08/17/2023
Stelara® (ustekinumab) IV	J3358	12/07/2021
Sunlenca® (lenacapavir) IV	J1961	02/16/2023
Synagis® (palivizumab)	90378	02/16/2023
Tecentriq® (atezolizumab)	J9022	02/16/2023
Tepezza™ (teprotumumab-trbw)	J3241	12/07/2021
Tezspire® (tezepelumab-ekko)	J2356	02/16/2023
Tofidence™ (tocilizumab-bavi)	Q5133	8/15/2024
Triptodur® (triptorelin)	J3316	02/16/2023
Trodelvy® (sacituzumab govitecan-hziy)	J9317	02/16/2023
Trogarzo® (ibalizumab-uiyk)	J1746	02/16/2023
Truxima® (rituximab-abbs)	Q5115	08/04/2020
Tysabri® (natalizumab)	J2323	05/26/2020
Tzield™ (teplizumab-mzwv)	J9381	05/18/2023

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Tyenne® (tocilizumab-aazg)	C9399, J3590	8/15/2024
Ultomiris® (ravulizumab-cwvz)	J1303	12/07/2021
Uplizna® (inebilzumab-cdon)	J1823	02/16/2023
Uptravi® (selexipag) IV	C9399, J3490	12/07/2021
Vectibix® (panitumumab)	J9303	02/16/2023
Velcade® (bortezomib)	J9041	12/01/2022
Veopoz™ (pozelimab-bbfd)	C9399, J3590	08/15/2024
Viltepso (viltolarsen)	J1427	05/16/2024
Vimizim™ (elosulfase alfa)	J1322	06/18/2019
Vpriv® (velaglucerase alfa)	J3385	06/18/2019
Vyepti® (eptinezumab-jjmr)	J3032	07/19/2022
Vyjuvek™ (beremagene-geperpavec-svdt)	J3401	02/15/2024
Vyondys 53 (golodirsen)	J1429	05/16/2024
Vyvgart™ (efgartigimod alfa-fcab)	J9332	12/01/2022
Vyvgart Hytrulo™ (efgartigimod alfa and hyaluronidase-qvfc)	J9334	08/17/2023
Xembify™ (immune globulin, human-klhw)	J1558	08/04/2020
Xgeva® (denosumab)	J0897	12/22/2020
Xolair® (omalizumab)	J2357	02/16/2023
Yervoy® (ipilimumab)	J9228	08/04/2020
Yondelis® (trabectedin)	J9352	02/16/2023
Zemaira® (alpha1-proteinase inhibitors)	J0256	06/18/2019
Zolgensma® (onasemmogene abeparvovec-xioi)	J3399	06/18/2019

History:	**Date:**	**Activity:**
Pharmacy and Therapeutics Committee	08/15/24	Revisions: Drugs added, Coding (eff 10/14/24)
Pharmacy and Therapeutics Committee	07/25/24	Revisions by Ad Hoc: Drugs removed, Coding (eff 07/25/24)
Pharmacy and Therapeutics Committee	05/16/24	Revisions: Drugs added, Coding (eff 07/15/24)
Pharmacy and Therapeutics Committee	02/15/24	Revisions: Drugs added, Coding (eff 04/16/24)
Pharmacy and Therapeutics Committee	11/16/23	Reviewed with Revisions: Drugs added, Coding (eff 01/15/24)
Pharmacy and Therapeutics Committee	08/17/23	Revisions: Drugs added, Coding (eff 10/16/23)
Pharmacy and Therapeutics Committee	05/18/23	Revisions: Drugs added, Coding (eff 07/18/23)
Pharmacy and Therapeutics Committee	02/16/23	Revisions: Drugs added, Coding (eff 04/18/23)
Pharmacy and Therapeutics Committee	12/01/22	Reviewed with Revisions: Criteria, Drugs added, Coding, Formatting (effective date 01/30/23)
Pharmacy and Therapeutics Committee	05/19/22	Revisions: Drugs added, Coding (effective date 07/19/2022)
Medical Policy Panel	12/07/21	Approved guideline
Clinical Pharmacist	11/04/21	Development

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Coding:

CPT: Various
HCPCS: Various

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

Resources:

Literature reviewed 11/16/23. 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.

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE:**	**12/07/21**
SECTION: ADMINISTRATIVE SPECIALTY MEDICATIONS	**LAST REVIEW DATE:**	**11/16/23**
	CURRENT EFFECTIVE DATE:	**10/14/24**
	LAST CRITERIA REVISION DATE:	**08/15/24**
NEXT ANNUAL REVIEW DATE: 4TH QTR 2024	**ARCHIVE DATE:**	

SITE OF SERVICE REQUIREMENTS FOR CERTAIN MEDICATIONS

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