Skip to main content

- · Contact us
- Español
 - · Contact us
 - Español

•

Explore Aetna sites

- · Individuals & Families
- · Affordable Care Act
- Medicare
- Medicaid
- Providers
- Employers
- · Agents & Brokers
- Careers
- About Us
- Individuals & Families
- Affordable Care Act
- Medicare
- Medicaid
- Providers
- Employers
- Agents & Brokers
- Careers
- About Us
- Join our network
 - Precertification overview
 - Precertification lists and CPT code search
 - Forms
 - Availity provider portal
 - Update your data
 - Utilization management
 - Provider referral directory
 - Epic payer platform
 - Overview
 - Smart Compare program
 - HEDIS measurements
 - Aetna specialty institutes
 - Aetna Aexcel designation
 - CAHPS[®] survey
- Claims, payment & reimbursements
 - Electronic claims
 - o Disputes and appeals
 - Cost estimator and fee schedules
 - Pharmacy claims
 - Dental claims
- o Pharmacy services
 - Update pharmacy data
 - Find prescription drug coverage
 - Clinical policy bulletin overview
 - Medical clinical policy bulletins
 - Dental clinical policy bulletins
 - Pharmacy clinical policy bulletins
 - Forms
 - o Medicare resources
 - Depression
 - Substance use
 - Suicide prevention

- Overview
 - Educational webinars
 - Provider education bulletins
 - Provider manuals
 - Behavioral health trainings
 - Health equity trainings
 - Risk adjustment training
 - State regulations
 - Federal regulations
- o OfficeLink updates newsletter
 - Podcasts
 - o Company news

Login

Login

Working with us

• Join our network

Precertification

- Precertification overview
- Precertification lists and CPT code search
- Forms

· Existing health care professionals

- Availity provider portal
- Update your data
- Utilization management
- Provider referral directory
- Epic payer platform

· Patient care programs & quality assurance

- Overview
- Smart Compare program
- HEDIS measurements
- Aetna specialty institutes
- Aetna Aexcel designation
- CAHPS[®] survey

Claims

- · Claims, payment & reimbursements
- Electronic claims
- Disputes and appeals
- · Cost estimator and fee schedules
- · Pharmacy claims
- Dental claims

Pharmacy

- · Pharmacy services
- · Update pharmacy data
- Find prescription drug coverage

•

Resources

Clinical policy bulletins

- · Clinical policy bulletin overview
- Medical clinical policy bulletins
- o Dental clinical policy bulletins
- Pharmacy clinical policy bulletins
- Forms
- · Medicare resources

Patient's mental health

- Depression
- Substance use
- o Suicide prevention

Education, trainings and manuals

- Overview
- o Educational webinars
- o Provider education bulletins
- Provider manuals
- Behavioral health trainings
- Health equity trainings
- Risk adjustment training

Regulations

- State regulations
- Federal regulations

.

News and Insights

- · OfficeLink updates newsletter
- Podcasts
- · Company news

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Drug infusion/Injection site of care policy

This page outlines the Site of Care for Specialty Drug Administration policy and the medications to which this policy applies. It provides the criteria used to determine the medical necessity of hospital outpatient administration as the site of service for identified specialty medications (See Site of Care for Specialty Drug Infusion/Injection applicable drug therapy below.)

Site of care

The starting dose(s) of the medications subject to this policy may be given at the physician's facility of choice only when multiple administrations are required and provided that the medication is available and not subject to limited distribution. For identified gene and cellular therapies, all doses (including the starting dose(s)) must be administered at an Aetna Institutes® Gene Based, Cellular and Other Innovative Therapy (GCIT®) Network listed in the policy apply. (See Aetna Institutes® GCIT Designated Centers below)

This includes hospital outpatient facilities, non-hospital outpatient facilities and home care. In the event the therapy is represented by a single administration, the policy applies to the first administration.

All subsequent doses will be subject to the Aetna Site of Care for Drug Administration policy, which requires the use of nonhospital outpatient facilities or home care.

Clinical rationale and documentation must be provided for review of Medical Necessity exceptions. (See Criteria for Medical Necessity below)

For identified gene and cellular therapies, Aetna Institutes® program GCIT Designated Network applies in place of medical necessity exception criteria. (See Aetna Institutes® GCIT Designated Centers below)

Site of care for specialty drug infusion/Injection applicable drug therapy

Actemra IV formulation – effective 1/1/2019

Adakveo - effective 2/13/2020

Adcetris - effective 8/1/2024

Aduhelm - effective 8/3/2021

Adzynma – effective 3/19/2024

Aldurazyme – effective 1/1/2020

Alpha 1 proteinase inhibitors (Glassia, Prolastin C, Aralast NP, Zemaira) - effective 1/1/2020

Amondys 45 - effective 6/1/2021

Amvuttra – effective 9/22/2022

Avsola (infliximab-axxg) - effective 9/1/2020

Bavencio – effective 7/1/2020

Benlysta IV formulation - effective 7/1/2019

Begvez^{GCIT} – effective 8/1/2024

BKEMV - effective 10/24/2024

Briumvi – effective 4/11/2023

CasgevyGCIT - effective 3/1/2024

Cerezyme - effective 1/1/2020

Cingair - effective 9/1/2020

Cinryze - effective 1/1/2020

Cosentyx IV - effective 1/1/2024

Crysvita - effective 7/13/2018 Elaprase – effective 1/1/2020

Elelyso - effective 1/1/2020

Elevidys GCIT effective 09/14/2023

Elfabrio - effective 8/1/2023

Enjaymo - effective 4/29/2022

Entyvio – effective 1/1/2019

Epysgli - effective 10/24/2024

Evkeeza – effective 5/7/2021

Exondys 51 - effective 1/11/2017

Fabrazyme – effective 1/1/2020

Fasenra (provider-administered) - effective 9/1/2020

Givlaari – effective 2/13/2020

Hemgenix^{GCIT} effective 3/17/2023

Herceptin – effective 8/1/2024

Hercessi - effective 8/1/2024

Herzuma - effective 08/1/2024

Imfinzi – effective 7/1/2020

Immune Globulins – effective 1/1/2017

Inflectra (infliximab-dvvb) - effective 7/1/2017

Jemperli – effective 7/1/2021

Kadcyla - effective 8/1/2024

Kaniinti - effective 8/1/2024

Kanuma - effective 1/1/2020

Kevtruda - effective 7/1/2020

Kisunla – effective 10/1/2024

Lamzede - effective 7/1/2023

Lanreotide - effective 9/1/2024

Lemtrada – effective 7/1/2017 Lenmeldy ^{GCIT} – effective 7/1/2024

Legembi – effective 04/5/2023

Logtorzi - effective 3/19/2024

Lumizyme - effective 1/1/2020

Lyfgenia^{GCIT} – effective 3/1/2024

Mepsevii – effective 1/1/2020

Naglazyme - effective 1/1/2020

Nexviazyme – effective 10/7/2021

Nucala (provider-administered) - effective 9/1/2020

Ocrevus - effective 05/23/2017

Ocrevus Zunovo - effective 01/07/2025

Ogivri – effective 8/1/2024

Onpattro – effective 08/23/2018

Ontruzant – effective 8/1/2024

Opdivo - effective 7/1/2020

Opdualag - effective 6/1/2022

Orencia IV formulation - effective 1/1/2019

Oxlumo – effective 3/17/2021

Perjeta – effective 8/1/2024

Piasky - effective 9/20/2024

Pombiliti - effective 12/15/2023

Oalsodv^{GCIT} – effective 7/1/2023

Radicava (edaravone IV) - effective 7/20/2017

Remicade (infliximab) - effective 7/1/2017

Renflexis (infliximab-abda) - effective 9/1/2017

Riabni - effective 8/1/2024

Rituxan - effective 8/1/2024

Rivfloza – effective 12/19/2023

Roctavian GCIT effective 10/2/2023

Ruxience - effective 8/1/2024

Sandostatin LAR - effective 8/1/2024

Saphnelo – effective 10/7/2021

Simponi Aria – effective 1/1/2019

Skysona^{GCIT} – effective 1/1/2023

Soliris – effective 1/1/2017

Somatuline Depot – effective 8/1/2024

Spinraza^{GCIT} – effective 7/1/2021

Tecentria – effective 7/1/2020

Tecentriq Hybreza – effective 01/10/2025

Tepezza – effective 7/1/2020

Tevimbra - effective 7/1/2024

Tezspire – effective 3/23/2022

Tofidence - effective 12/29/2023

Trazimera - effective 8/1/2024 Truxima - effective 8/1/2024

Tyenne – effective 7/1/2024 Tyruko - effective 11/28/2023 Tysabri – effective 7/1/2017 Ultomiris - effective 3/15/2019 Uplizna - effective 9/1/2020 Veopoz - effective 11/10/2023 Viltepso - effective 11/10/2020 Vimizim - effective 1/1/2020 Vpriv – effective 1/1/2020 Vyepti – effective 7/1/2020 Vyondys 53 – effective 3/1/2019 Vyvgart Hyrtulo (CIDP indication only) effective 11/1/2024 Xenpozyme – effective 12/2/2022 Xolair – effective 9/1/2020 Yervoy - effective 7/1/2020 Yimmugo – effective 10/1/2024 Zolgensma^{GCIT} – effective 7/1/2019 Zynteglo^{GCIT} effective 1/1/2023 Zynyz - effective 7/1/2023

GCIT Product available for administration at Aetna Institutes[®] Gene Based, Cellular and Other Innovative Therapy (GCIT[®]) Designated Centers.

Aetna Institutes® GCIT Designated Centers

Beqvez Qalsody
Casgevy Roctavian
Elevidys Skysona
Hemgenix Spinraza
Lenmeldy Zolgensma
Lyfgenia Zynteglo
Luxturna

For more information on Aetna Institutes® Gene Based, Cellular and Other Innovative Therapy (GCIT®) Designated Centers refer to our Aetna Institutes page.

For the GCIT network facility listing, refer to:

GCIT network facility listing (PDF)

GCIT network facility listing - Spanish (PDF)

Criteria for medical necessity

- 1. The member is new to therapy or reinitiating therapy after not being on therapy for at least 6 months. For Xolair only, the member is new to therapy or reinitiating therapy after not being on therapy for at least 3 months.
- 2. The member is switching to a product they haven't received before.*
- 3. The member's had a gap in therapy.*
- 1. The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.
- 2. The member either has immunoglobulin A (IgA) deficiency with anti-IgA antibodies* or has developed anti-drug antibodies* which increases the risk for infusion related reactions.
- 3. The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- 4. The member has severe venous access issues that require the use of a special intervention.*
- 5. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the administration AND the patient does not have access to a caregiver.
- 6. For members receiving Perjeta or trastuzumab (Herceptin, Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera), the member is receiving provider-administered combination chemotherapy.
- 7. For members receiving Adcetris or rituximab (Riabni, Rituxan, Ruxience, Truxima), the member is receiving provider-administered chemotherapy or other drug therapies at the same visit.
- 8. For members receiving Perjeta, trastuzumab, or rituximab, the member is less than 14 years of age.
- 9. For members receiving an immune checkpoint inhibitor (Bavencio, Imfinzi, Jemperli, Keytruda, Libtayo, Loqtorzi, Opdivo, Opdualag, Tecentrig, Tecentrig Hybreza, Tevimbra, Yervoy, Zynyz), ANY of the following additional criteria also apply:
 - 1. The member is within the initial 6 months of starting therapy;
 - 2. The member is continuing on a maintenance regimen that includes provider administered combination chemotherapy including but not limited to: i. Tecentriq or Tecentriq Hyberza used in combination with bevacizumab for non-small cell lung cancer (NSCLC); ii. Tecentriq or Tecentriq Hyberza used in combination with paclitaxel protein-bound for breast cancer; iii. Keytruda in combination with pemetrexed for NSCLC;
 - 3. The member is experiencing severe toxicity requiring continuous monitoring (e.g., Grade 2-4 bullous dermatitis, transaminitis, pneumonitis, Stevens-Johnson syndrome, acute pancreatitis, primary adrenal insufficiency aseptic meningitis, encephalitis, transverse myelitis, myocarditis, pericarditis, arrhythmias, impaired ventricular function, conduction abnormalities).

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- 1. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration
- 2. Medical records supporting the member has IgA antibodies or has developed anti-drug antibodies
- 3. Medical records supporting the member is medically unstable
- 4. Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
- 5. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- 6. Medical records supporting the member is receiving provider administered combination chemotherapy

For situations where administration of the medication does not meet the criteria for outpatient hospital administration, coverage for the medication is provided when administered in alternative sites such as physician office, home infusion or ambulatory care.

Drug	Indication	Days allowed
Tocilizumab	Rheumatoid arthritis (RA) only	99 days
Tocilizumab	Polyarticular Juvenile Idiopathic Arthritis(PJIA) only	99 days
Tocilizumab	Systemic Juvenile Idiopathic Arthirits (SJIA) only	50 days
Tocilizumab	Castleman's disease	50 days
Tocilizumab	Immunotherapy-related inflammatory arthritis only	99 days
Adzynma	Prophylactic treatment of congenital thrombotic thrombocytopenic purpura (cTTP) only	99 days
Aldurazyme	Mucopolysaccharidosis I	54 days

Drug

Elfabrio

	Drug	Indication	Days allowed	
Elaprase	2.09	Hunter syndrome	54 days	
Elfabrio		Fabry disease	106 days	
Fabrazyme		Fabry disease	106 days	
Infliximab		Takayasu only	85 days	
Kanuma		LAL deficiency	50 days	
Lamzede		Alpha-mannosidosis	54 days	
Lumizyme		Pompe disease	106 days	
Mepsevii		Mucopolysacaridosis VII	50 days	
Naglazyme		Mucopolysacaridosis VI	54 days	
Nexviazyme		Pompe disease	106 days	
Oxlumo		Primary hyperoxaluria type I	60 days	
Pombiliti		Pompe disease	106 days	
Vimizim		Mucopolysacaridosis IVA	82 days	
Vpriv		Gaucher disease type I	50 days	
Vyepti		Migraine prevention	50 days	
Xenpozyme		Acid sphingomyelinase deficiency (ASMD)	119 days	
Xolair		Asthma, chronic idiopathic urticaria	60 days	
Jemperli, Ke	eckpoint Inhibitors (Bavencio, Imfinzi, ytruda, Libtayo, Loqtorzi, Opdivo, Opdualag, centriq Hybreza, Tevimbra, Yervoy, and Zynyz)	All indications	6-month initial authorization, then up to 45 day renewal	
Drug	Tocilizumab			
Indication	Rheumatoid arthritis (RA) only			
Days allowed	99 days			
Drug	Tocilizumab			
Indication	Polyarticular Juvenile Idiopathic Arthritis(PJIA) only			
Days allowed	99 days			
Drug	Tocilizumab			
Indication	Systemic Juvenile Idiopathic Arthirits (SJIA) only			
Days allowed	50 days			
Drug	Tocilizumab			
Indication	Castleman's disease			
Days allowed	50 days			
Drug	Tocilizumab			
Indication	Immunotherapy-related inflammatory arthritis only			
Days allowed	99 days			
Drug	Adzynma			
Indication	Prophylactic treatment of congenital thrombotic thrombocytopenic purpura (cTTP) only			
Days allowed	99 days			
Drug	Aldurazyme			
Indication	Mucopolysaccharidosis I			
Days allowed	54 days			
Drug	Elaprase			
Indication	Hunter syndrome			
Days allowed	54 days			
D	TH-L-1			

Indication Fabry disease

Days allowed 106 days Drug Fabrazyme

Indication Fabry disease

Days
106 days

allowed Tob days

Drug Infliximab

Indication Takayasu only

Days allowed 85 days
Drug Kanuma

Indication LAL deficiency

Days allowed 50 days Lamzede

Indication Alpha-mannosidosis

Days allowed 54 days
Drug Lumizyme
Indication Pompe disease

Days allowed Drug Mepsevii

Indication Mucopolysacaridosis VII

Days allowed 50 days Drug Naglazyme

Indication Mucopolysacaridosis VI

Days allowed 54 days

Drug Nexviazyme **Indication** Pompe disease

Days allowed Drug Oxlumo

Indication Primary hyperoxaluria type I

Days allowed 60 days
Drug Pombiliti
Indication Pompe disease

Days allowed Drug Vimizim

Indication Mucopolysacaridosis IVA

Days allowed 82 days
Drug Vpriv

Indication Gaucher disease type I

Days allowed 50 days

Drug Vyepti

Indication Migraine prevention

Days allowed 50 days
Drug Xenpozyme

Indication Acid sphingomyelinase deficiency (ASMD)

Days allowed 119 days Drug Xolair

Indication Asthma, chronic idiopathic urticaria

Days allowed 60 days

Drug Immune Checkpoint Inhibitors (Bavencio, Imfinzi, Jemperli, Keytruda, Libtayo, Loqtorzi, Opdivo, Opdualag,

Tecentriq, Tecentriq Hybreza, Tevimbra, Yervoy, and Zynyz)

Indication All indications

Days allowed 6-month initial authorization, then up to 45 day renewal

Medication billing procedure codes

Applicable codes

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