

Clinical Policy: Roflumilast (Daliresp, Zoryve)

Reference Number: CP.PMN.46

Effective Date: 11.01.11 Last Review Date: 08.25

Line of Business: Commercial, HIM, Medicaid Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Roflumilast (Daliresp[®], Zoryve[®]) is a selective phosphodiesterase 4 inhibitor.

FDA Approved Indication(s)

Daliresp is indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Zoryve is indicated:

- 0.3% cream: for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.
- 0.15% cream: for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.
- 0.05% cream: for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.
- Foam:
 - o For the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older
 - For the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older

Limitation(s) of use:

- Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.
- Daliresp 250 mcg is a starting dose for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that roflumilast, Daliresp, and Zoryve are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. Chronic Obstructive Pulmonary Disease (must meet all):
 - 1. Request is for roflumilast tablet (Daliresp);
 - 2. Diagnosis of COPD;



- 3. Age \geq 18 years;
- 4. Current (within the past 30 days) forced expiratory volume in one second (FEV₁) < 50% predicted;
- 5. Member meets one of the following (a or b):*
 - *For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. Failure of triple inhaled therapy consisting of a combination of a long-acting beta₂-agonist (LABA), long-acting antimuscarinic antagonist (LAMA), and inhaled corticosteroid (ICS) at up to maximally indicated doses;
 - b. Both i and ii:
 - i. Failure of dual inhaled therapy consisting of a combination of a LABA and LAMA at up to maximally indicated doses;
 - ii. Current (within the past 30 days) blood eosinophil count < 100 cells/uL;
- 6. Daliresp is prescribed concurrently with a long-acting bronchodilator (i.e., LABA or LAMA);
- 7. For brand Daliresp requests, member must use generic roflumilast, unless contraindicated or clinically significant adverse effects are experienced;
- 8. Dose does not exceed both of the following (a and b):
 - a. 500 mcg per day;
 - b. 1 tablet per day.

Approval duration: 12 months

B. Plaque Psoriasis (must meet all):

- 1. Request is for roflumilast 0.3% cream or foam (Zoryve);
- 2. Diagnosis of plaque psoriasis;
- 3. Member has body surface area involvement $\leq 20\%$ ($\leq 25\%$ if scalp is involved);
- 4. Prescribed by or in consultation with a dermatologist or rheumatologist;
- 5. Age is one of the following (a or b):
 - a. Cream: ≥ 6 years;
 - b. Foam: ≥ 12 years;
- 6. Member meets one of the following (a or b):*
 - *For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. Failure of both of the following (i and ii) used concurrently, unless clinically significant adverse effects are experienced or all are contraindicated:
 - i. Medium to ultra-high potency topical corticosteroid (see Appendix B);
 - ii. Calcipotriene, calcitriol, or tazarotene;
 - b. For face or intertriginous areas (e.g., genitals, armpits, forearms, and groin): Failure of a topical calcineurin inhibitor* (*see Appendix B*), unless contraindicated or clinically adverse effects are experienced;
 - *Prior authorization may be required for topical calcineurin inhibitors
- 7. Request does not exceed 1 tube (cream) or can (foam) per month.

Approval duration: 12 months

C. Seborrheic Dermatitis (must meet all):

- 1. Request is for roflumilast foam (Zoryve);
- 2. Diagnosis of seborrheic dermatitis;



- 3. Member has body surface area involvement $\leq 20\%$;
- 4. Prescribed by or in consultation with a dermatologist;
- 5. Age \geq 9 years;
- 6. Failure of both of the following (a and b), unless clinically significant adverse effects are experienced or all are contraindicated:*
 - *For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. Topical antifungal (see Appendix B);
 - b. Topical corticosteroid (see Appendix B);
- 7. Request does not exceed 1 can per month.

Approval duration: 12 months

D. Atopic Dermatitis (must meet all):

- 1. Request is for roflumilast 0.15% or 0.05% cream (Zoryve);
- 2. Diagnosis of atopic dermatitis;
- 3. Age is one of the following (a or b):
 - a. 0.15% cream: ≥ 6 years;
 - b. 0.05% cream: 2 to < 6 years;
- 4. Failure of both of the following (a and b), each tried for 2 weeks, unless clinically significant adverse effects are experienced or all are contraindicated:*

 *For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
 - a. One of the following (i or ii), unless involved areas include the face, neck, or intertriginous areas:
 - i. Age 2 to < 6 years: Two generic medium potency topical corticosteroids of different molecular identities (see Appendix B);
 - ii. Age ≥ 6 years: Two generic medium to very high potency topical corticosteroids of different molecular identities (see Appendix B);
 - b. Topical tacrolimus;^
 - ^Prior authorization may be required for topical tacrolimus
- 5. Dose does not exceed 1 tube per month.

Approval duration: 12 months

E. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:
 CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND



criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (must meet all):

- 1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- 2. Request is for roflumilast tablet (Daliresp);
- 3. Member is responding positively to therapy;
- 4. For brand Daliresp requests, member must use generic roflumilast, unless contraindicated or clinically significant adverse effects are experienced;
- 5. If request is for a dose increase, new dose does not exceed both of the following (a and b):
 - a. 500 mcg per day;
 - b. 1 tablet per day.

Approval duration: 12 months

B. Plaque Psoriasis (must meet all):

- 1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- 2. Request is for roflumilast 0.3% cream or foam (Zoryve);
- 3. Member is responding positively to therapy;
- 4. If request is for a dose increase, new dose does not exceed 1 tube (cream) or can (foam) per month.

Approval duration: 12 months

C. Seborrheic Dermatitis (must meet all):

- 1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- 2. Request is for roflumilast foam (Zoryve);
- 3. Member is responding positively to therapy;
- 4. If request is for a dose increase, new dose does not exceed 1 can per month.

Approval duration: 12 months



D. Atopic Dermatitis (must meet all):

- 1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is receiving benefit from the referenced states for the applicable product and regulation (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- 2. Request is for roflumilast 0.15% or 0.05% cream (Zoryve);
- 3. Member is responding positively to therapy;
- 4. If request is for a dose increase, new dose does not exceed 1 tube per month.

Approval duration: 12 months

E. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:
 CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration FEV₁: forced expiratory volume in one second

ICS: inhaled corticosteroid
LABA: long-acting beta2-agonist

LAMA: long-acting antimuscarinic antagonist



Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business

and may require prior authorization.

COPD	D · D ·	D 1:://		
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose		
ICS/LABA Combinations				
fluticasone/salmeterol	Refer to prescribing information	Refer to		
(Advair Diskus®)		prescribing		
Breo Ellipta® (fluticasone/		information		
vilanterol)				
budesonide/formoterol				
(Symbicort®)				
Dulera®*(mometasone/	Doses of 10 mcg formoterol/400 mcg	The optimal dose		
formoterol)	mometasone and 10 mcg formoterol/	has not been		
	200 mcg mometasone, each inhaled	established		
	BID, have been studied			
	LABA/LAMA Combinations			
Bevespi Aerosphere®	Refer to prescribing information	Refer to		
(formoterol/glycopyrrolate)		prescribing		
Utibron Neohaler®		information		
(indacaterol/glycopyrrolate)				
Anoro Ellipta®				
(vilanterol/umeclidinium)				
Stiolto Respimat®				
(olodaterol/tiotropium)				
	LAMAs	T= 2		
Tudorza Pressair®	Refer to prescribing information	Refer to		
(aclidinium bromide)		prescribing		
Seebri Neohaler®		information		
(glycopyrrolate)				
Spiriva Respimat®/				
HandiHaler® (tiotropium)	_			
Incruse Ellipta				
(umeclidinium)				
D ® (C)	LABAs The Control of	D.C.		
Brovana® (arformoterol)	Refer to prescribing information	Refer to		
Arcapta Neohaler®		prescribing		
(indacaterol)	-	information		
Striverdi Respimat®				
(olodaterol)	4			
Serevent Diskus®				
(salmeterol)				



COPD			
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose	
ICS/LABA/LAMA Combinations			
Trelegy™ Ellipta® (fluticasone/umeclidinium/ vilanterol)	1 inhalation by mouth QD	1 inhalation/day	
PLAQUE PSORIASIS			
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose	
calcipotriene (Dovonex®) cream, ointment, solution	Apply topically to the affected area(s) BID	100 g/week	
calcitriol (Vectical [™]) ointment	Apply topically to the affected area(s) BID	200 g/week	
tazarotene (Tazorac®) gel, cream	Apply topically to the affected area(s) QHS	Once daily application	
Ultra-High Potency Topical			
augmented betamethasone dipropionate 0.05% (Diprolene®, Alphatrex®) ointment, gel clobetasol propionate 0.05% (Temovate®, Temovate E®) cream, ointment, gel, solution diflorasone diacetate 0.05% (Apexicon®) ointment halobetasol propionate 0.05% (Ultravate®) cream, ointment	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks	
High Potency Topical Cortic			
augmented betamethasone dipropionate 0.05% (Diprolone®, Diprolene® AF) cream, lotion betamethasone dipropionate 0.05% ointment desoximetasone (Topicort®) 0.25%, 0.05% cream, ointment, gel diflorasone 0.05% (Apexicon E®) cream	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks	



PLAQUE PSORIASIS		
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluocinonide acetonide		
0.05% cream, ointment, gel,		
solution		
triamcinolone acetonide		
0.5% (Aristocort®,		
Kenalog®) cream, ointment		
	tency Topical Corticosteroids	
betamethasone dipropionate	Apply topically to the affected area(s)	Should not be
0.05% cream	BID	used for longer
desoximetasone 0.05%		than 2
(Topicort®) cream, ointment,		consecutive
gel		weeks
fluocinolone acetonide		
0.025% (Synalar®) cream,		
ointment		
fluticasone propionate 0.05%		
(Cutivate®) cream		
mometasone furoate 0.1%		
(Elocon®) cream, lotion,		
ointment		
triamcinolone acetonide		
0.1%, 0.25%, 0.5%		
(Aristocort [®] , Kenalog [®])		
cream, ointment		
	+ (Vitamin D Analog or Retinoid)	
Enstilar® (calcipotriene	Apply topically to affected areas QD	60 g/4 days
0.005% and betamethasone	for up to 4 weeks. Avoid use on face,	
dipropionate 0.064%) foam	groin, axillae, skin treatment site with	
	atrophy present, or with occlusive	
	dressing unless directed by a healthcare	
	provider	
Duobrii® (halobetasol	Apply a thin layer of lotion once daily	50 g/week
propionate 0.01% and	to affected areas until control is	
tazarotene 0.045%) lotion	achieved	
Topical Calcineurin Inhibito		
tacrolimus (Protopic®)	Apply twice daily to psoriatic lesions	2
(off-label)	of the face and intertriginous areas	applications/day
pimecrolimus (Elidel®)	Apply twice daily to affected	2
(off-label)	intertriginous areas	applications/day



SEBORRHEIC DERMATITIS				
Drug Name	Dosing Regimen		Dose Limit/	
			Maximum Dose	
Topical Antifungal	I = 0		T = 0	
ketoconazole (Nizoral® A-D,	Refer to prescribing information		Refer to	
Extina [®] , Ketodan [®] ,			prescribing	
Xolegel [™]) 1-2% shampoo, 1-			information	
2% cream, foam, gel	-			
ciclopirox 1-1.5% shampoo,				
0.77% gel, 1% cream	-			
miconazole 2% solution	-			
clotrimazole (Lotrimin®) 1%				
cream, ointment, solution				
Topical Corticosteroids	Dofon to mass ::	hing information	Refer to	
betamethasone dipropionate 0.05% cream, gel, lotion,	Keier to prescri	bing information		
			prescribing information	
spray; betamethasone valerate 0.12% foam, 0.1%			IIIIOIIIIatioii	
cream, lotion				
clobetasol propionate	-			
(Temovate [®] , Temovate E [®])				
0.05% cream, ointment, gel,				
solution, shampoo				
desonide (Desowen®,				
Tridesilon [®] , Verdeso [®])				
0.05% cream, foam, gel,				
lotion, ointment				
hydrocortisone (NuZon®,				
NuCort®) 0.5-2.5% cream,				
ointment, lotion				
fluocinolone (Synalar®)				
0.01% shampoo, lotion,				
cream				
ATOPIC DERMATITIS				
Drug Name		Dosing Regimen	Dose Limit/	
			Maximum Dose	
Very High Potency Topical C	orticosteroids			
augmented betamethasone 0.05%		Apply topically to the	Varies	
(Diprolene®) ointment, gel, lotion		affected area(s) BID		
clobetasol propionate 0.05% (Temovate®)				
cream, ointment, gel, solution	<u> </u>			
diflorasone diacetate 0.05% (Apexicon E®				
ointment				
fluocinonide 0.1% (Vanos®) cream				



ATODIC DEDMATITIC		
ATOPIC DERMATITIS	Desing Peginson	Dogo Limit/
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
halobetasol propionate 0.05% (Ultravate®)		Maximum Bosc
cream, ointment		
High Potency Topical Corticosteroids		
amcinonide 0.1% ointment, lotion	Apply topically to the	Varies
augmented betamethasone 0.05% (Diprolene®	affected area(s) BID	
AF) cream, ointment, gel, lotion		
betamethasone valerate 0.1%, 0.12%		
(Luxiq®) ointment, foam		
clobetasol propionate 0.025% (Impoyz®)		
cream		
diflorasone 0.05% (Apexicon E®, Psorcon®)		
cream		
fluocinonide acetonide 0.05% cream,		
ointment, gel, solution		
fluticasone propionate 0.005% cream,		
ointment		
halcinonide 0.1% cream, ointment, solution		
(Halog®)		
halobetasol propionate 0.01% lotion		
(Bryhali [®])		
mometasone furoate 0.1% ointment		
triamcinolone acetonide 0.5% (Triderm®)		
cream, ointment		
Medium Potency Topical Corticosteroids		1
clocortolone pivalate 0.1% cream	Apply topically to the	Varies
desoximetasone 0.05%, 0.025% (Topicort®)	affected area(s) BID	
cream, ointment, gel		
fluocinolone acetonide 0.025% (Synalar®)		
cream, ointment		
flurandrenolide 0.05% lotion, ointment		
(Cordran [®])		
hydrocortisone valerate 0.2% cream		
mometasone 0.1% cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% cream,		
ointment		
Topical Calcineurin Inhibitors	1 1 1 1	
tacrolimus (Protopic®)	Apply a thin layer to	Varies
0.03% or 0.1% ointment	affected area BID.	
	Age 2-15 years, use	
	0.03% ointment only.	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.



*Off-label

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): moderate to severe liver impairment (Child-Pugh B or C)
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Daliresp	COPD	500 mcg PO QD (starting treatment with 250 mcg QD for 4 weeks and increasing to 500 mcg QD thereafter may reduce the rate of discontinuation in some patients)	500 mcg/day
Zoryve	Plaque psoriasis	Apply 0.3% cream or foam to affected areas once daily	Once daily application
	Seborrheic dermatitis	Apply foam to affected areas once daily	Once daily application
	Atopic dermatitis	Apply 0.15% cream (adult and pediatric patients 6 years of age and older) or 0.05% (pediatric patients 2 to < 6 years of age) to affected areas once daily	Once daily application

VI. Product Availability

Drug Name	Availability
Daliresp	Tablets: 250 mcg, 500 mcg
Zoryve	Cream (0.05%, 0.15%, 0.3%): 60 g tube
	Foam (0.3%): 60 g can

VII. References

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Reviews, Revisions, and Approvals	Date	P&T
		Approval
		Date
3Q 2021 annual review: no significant changes; added Commercial	03.17.21	08.21
line of business; references reviewed and updated.		
3Q 2022 annual review: no significant changes; references reviewed	03.30.22	08.22
and updated.		
RT4: added criteria for newly FDA-approved dosage form (Zoryve	08.08.22	11.22
cream) and indication of plaque psoriasis.		
Template changes applied to other diagnoses/indications and	11.07.22	
continued therapy section.		
3Q 2023 annual review: no significant changes; added HIM line of	04.18.23	08.23
business; added redirection to generic roflumilast for brand Daliresp		
requests; references reviewed and updated.		
RT4: updated age requirement from 12 to 6 years per updated	10.17.23	
pediatric extension on Zoryve label.		
RT4: added criteria for newly FDA-approved dosage form (Zoryve	01.16.24	02.24
topical foam) and indication of seborrheic dermatitis.		
3Q 2024 annual review: no significant changes; revised policy/	07.25.24	08.24
criteria section to also include generic roflumilast; references		
reviewed and updated.		
RT4: added criteria for newly FDA-approved dosage form (Zoryve		
0.15% cream) and indication of atopic dermatitis; specified that only		
the 0.3% cream should be used for plaque psoriasis per updated FDA		
labeling.		
3Q 2025 annual review: RT4: added newly FDA-approved indication	06.24.25	08.25
of plaque psoriasis for Zoryve foam; for COPD, added step therapy		
bypass for generic roflumilast tablet for IL HIM per IL HB 5395;		



Reviews, Revisions, and Approvals		P&T
		Approval Date
		Date
removed econazole, luliconazole, oxiconazole, and sulconazole from		
Appendix B as there is insufficient evidence for the use of these		
agents in seborrheic dermatitis; references reviewed and updated.		
Added step therapy bypass for all step therapy requirements and		
agents for IL HIM per IL HB 5395.		
RT4: added Zoryve 0.05% cream to criteria with pediatric extension	10.21.25	
down to 2 years of age for atopic dermatitis.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.



Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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