

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.
- 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 (Zorvve):
- 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% cream (Zoryve);
- 2. Diagnosis of atopic dermatitis;
- 3. Age \geq 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. Two generic medium to very high potency topical corticosteroids of different molecular identities (*see Appendix B*), unless involved areas include the face, neck, or intertriginous areas;
 - 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% 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.

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



COPD				
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose		
I	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,	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks		
ointment				
High Potency Topical Cortic	osteroids			
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 fluocinonide acetonide 0.05% cream, ointment, gel, solution	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		
triamcinolone acetonide				
0.5% (Aristocort [®] ,				
Kenalog®) cream, ointment				
Medium/Medium to High Potency 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	rs			
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				
ketoconazole (Nizoral® A-D,	Refer to prescribing information			
Extina [®] , Ketodan [®] ,				



Dosing Regimen Dosing Regimen Dose Limit/ Maximum Dose	SEBORRHEIC DERMATITIS			
Xolegel N 1-2% shampoo, 1-2% cream, foam, gel ciclopirox 1-1.5% shampoo, 0.77% gel, 1% cream miconazole 2% solution clotrimazole (Lotrimin®) 1% cream, ointment, solution	Drug Name	Dosing Regime	en	
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 betamethasone dipropionate 0.05% cream, gel, lotion, spray; betamethasone valerate 0.12% foam, 0.1% 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 Corticosteroids augmented betamethasone 0.05% (Cliprolen®) ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution	TV			
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cream ATOPIC DERMATITIS Drug Name Dosing Regimen Dose Limit/ Maximum Dose Very High Potency Topical Corticosteroids augmented betamethasone 0.05% (Diprolene®) ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution Varies	fluocinolone (Synalar®)			
ATOPIC DERMATITIS Drug Name Dosing Regimen Dose Limit/ Maximum Dose Very High Potency Topical Corticosteroids augmented betamethasone 0.05% (Diprolene®) ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution Varies	0.01% shampoo, lotion,			
Drug Name Dosing Regimen Dose Limit/Maximum Dose Very High Potency Topical Corticosteroids augmented betamethasone 0.05% Apply topically to the affected area(s) BID Varies (Diprolene®) ointment, gel, lotion affected area(s) BID clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution affected area(s) BID	cream			
Wery High Potency Topical Corticosteroids augmented betamethasone 0.05% (Diprolene®) ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution Maximum Dose Maximum Dose Varies	ATOPIC DERMATITIS			
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augmented betamethasone 0.05% (Diprolene®) ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution Apply topically to the affected area(s) BID				Maximum Dose
(Diprolene®) ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution affected area(s) BID	Very High Potency Topical Co	orticosteroids		
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution	augmented betamethasone 0.03	5%	Apply topically to the	Varies
cream, ointment, gel, solution	=			
cream, ointment, gel, solution				
	·			
diflorasone diacetate 0.05% (Apexicon E [®])	diflorasone diacetate 0.05% (Apexicon E [®])			
ointment	· -			
	fluocinonide 0.1% (Vanos®) cream		1	
	halobetasol propionate 0.05% (Ultravate®		1	
	cream, ointment			
High Potency Topical Corticosteroids				
amcinonide 0.1% ointment, lotion Varies				Varies



ATOPIC DERMATITIS		
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
augmented betamethasone 0.05% (Diprolene® 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	Apply topically to the affected area(s) BID	
triamcinolone acetonide 0.5% (Triderm®)		
cream, ointment		
Medium Potency Topical Corticosteroids		
clocortolone pivalate 0.1% cream desoximetasone 0.05%, 0.025% (Topicort®) 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	Apply topically to the affected area(s) BID	Varies
Topical Calcineurin Inhibitors		
tacrolimus (Protopic®) 0.03% or 0.1% ointment	Apply a thin layer to affected area BID. Age 2-15 years, use 0.03% ointment only.	Varies

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 to affected areas once daily	Once daily application

VI. Product Availability

Drug Name	Availability
Daliresp	Tablets: 250 mcg, 500 mcg
Zoryve	Cream (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 line of business; references reviewed and updated.	03.17.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	03.30.22	08.22
RT4: added criteria for newly FDA-approved dosage form (Zoryve cream) and indication of plaque psoriasis.	08.08.22	11.22
Template changes applied to other diagnoses/indications and continued therapy section.	11.07.22	
3Q 2023 annual review: no significant changes; added HIM line of business; added redirection to generic roflumilast for brand Daliresp requests; references reviewed and updated.	04.18.23	08.23
RT4: updated age requirement from 12 to 6 years per updated pediatric extension on Zoryve label.	10.17.23	
RT4: added criteria for newly FDA-approved dosage form (Zoryve topical foam) and indication of seborrheic dermatitis.	01.16.24	02.24
3Q 2024 annual review: no significant changes; revised policy/ 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	07.25.24	08.24
the 0.3% cream should be used for plaque psoriasis per updated FDA labeling.		
3Q 2025 annual review: RT4: added newly FDA-approved indication of plaque psoriasis for Zoryve foam; for COPD, added step therapy bypass for generic roflumilast tablet for IL HIM per IL HB 5395; 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.	06.24.25	08.25

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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