

Delgocitinib (ANZUPGO) Cream in Chronic Hand Eczema National Drug Mini-Monograph

December 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. The Product Information or other resources should be consulted for detailed and most current drug information.

Abbreviations: AC, active-controlled; ARD, absolute risk difference; AWP, Average Wholesale Price; CFB, change from baseline; CO, crossover; DB, double-blind; DLQI-4, Dermatology Life Quality Index improvement by 4 points (considered to be the minimal clinically important difference for inflammatory skin diseases); ESCD, European Society of Contact Dermatitis; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; GOR, grade of recommendation; HECSI, Hand Eczema Severity Index; HESD Itch, weekly average Hand Eczema Symptom Diary itch score (range 0 to 10); IGA-CHE, Investigator's Global Assessment for Chronic Hand Eczema; MN, multinational; NMSC, nonmelanoma skin cancer; Oint, ointment; PC, placebo-controlled; Q, GRADE quality of evidence (H, high; M, medium; L, low; VL, very low); RCT, randomized clinical trial

FDA PRESCRIBING INFORMATION¹

Description / MOA	Janus kinase (JAK) inhibitor (JAK1, JAK2, JAK3, and tyrosine kinase 2 [TYK2]). Exact mechanism in chronic hand eczema (CHE) is unknown.
Indication Under Review	Topical treatment of moderate to severe CHE in adults who have had an inadequate response to topical corticosteroids, or for whom topical corticosteroids are not advisable.
Dosage Regimen	Do not use more than 30 grams per 2 weeks or 60 grams per month. Apply a thin layer twice daily to the affected areas only on the hands and wrists.
Dosage Forms Under Review	Cream 2%
Pretreatment Procedures	<ul style="list-style-type: none"><input type="checkbox"/> Complete any necessary guideline-recommended immunizations, including herpes zoster vaccinations.<input type="checkbox"/> Consider viral hepatitis screening. Not recommended for use in patients with active hepatitis B or hepatitis C.<input type="checkbox"/> Consider lipid panel.
Treatment Monitoring	<ul style="list-style-type: none"><input type="checkbox"/> Infections<input type="checkbox"/> Viral hepatitis reactivation<input type="checkbox"/> Nonmelanoma skin cancer (NMSC)<input type="checkbox"/> Increases in total cholesterol, low-density lipoprotein, cholesterol, and triglycerides.

EFFICACY CONSIDERATIONS

Trial	Efficacy and safety of topical delgocitinib cream versus oral alitretinoin capsules in adults with severe chronic hand eczema (DELTA FORCE): a 24-week, randomised, head-to-head, phase 3 trial²
Design	24-week, phase 3, MN, single (assessor)-blind, active-controlled RCT Masked assessors rated IGA-CHE scores, and unmasked assessors made treatment decisions.
Primary Endpoint	Change in Hand Eczema Severity Index (HECSI) score from baseline to Week 12
Population	<i>Major Inclusion Criteria:</i> Adults ≥ 18 years, severe CHE (defined as IGA-CHE of 4), either documented inadequate response or medical inadvisability to topical corticosteroids. <i>Major Exclusion Criteria:</i> Concurrent skin diseases on the hands, previous treatment with systemic or topical JAK inhibitors, contraindication for alitretinoin. <i>Baseline Characteristics (N = 513):</i> Age 45.0 years, 35% male, 93% White, 11% North American, duration of CHE 4.0 years, 96% DLQI ≥ 4 . CHE subtype: 29% irritant contact dermatitis; 24% atopic hand eczema, 22% allergic contact dermatitis, 12% hyperkeratotic eczema, 11% vesicular hand eczema (pompholyx/dyshidrotic eczema).
Interventions	Delgocitinib cream 20 mg/g every 12 hours to affected areas regardless of clearance status up to Week 16. From Week 16 to 24, treatment was continued if the IGA-CHE score was ≥ 2 and an unmasked investigator deemed the patient could benefit from continued treatment. versus Alitretinoin 30 mg PO once daily regardless of clearance status up to Week 12. Dose could be reduced to 10 mg in case of an unacceptable adverse event. Alitretinoin was discontinued in patients who developed depression, mood disturbance, psychosis, or aggression.

	Treatment was stopped at Week 16 for delgocitinib or Week 12 for alitretinoin if IGA-CHE treatment success was achieved. IGA-CHE treatment success was defined as IGA-CHE score of 0/Clear or 1/Almost Clear with ≥ 2 -step improvement from baseline. Patients who relapsed (IGA-CHE ≥ 2) reinitiated and continued treatment up to Week 24.																																				
Co-therapy	Emollients were permitted. Topical corticosteroids, topical calcineurin inhibitors, and systemic immunosuppressive or immunomodulating drugs were not allowed.																																				
Results	<p>Week-12 or Week-24 Efficacy Results</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Delgocitinib Cream N = 250</th> <th>Alitretinoin N = 253</th> <th>RR (95% CI)</th> <th>ARD (95% CI)</th> <th>Q</th> </tr> </thead> <tbody> <tr> <td>CFB in HECSI score, Wk 12</td> <td>-67.6 [n = 249]</td> <td>-51.5 [n = 250]</td> <td>—</td> <td>-16.1 (-23.3, -8.9)</td> <td>H</td> </tr> <tr> <td>HECSI-90, Wk 12</td> <td>96/249 (39%)</td> <td>65/250 (26%)</td> <td>1.5 (1.14, 1.93)</td> <td>12.6 (4.3, 20.8)</td> <td>M^β</td> </tr> <tr> <td>IGA-CHE Treatment Success, Wk 12</td> <td>68/250 (27%)</td> <td>42/253 (17%)</td> <td>1.6 (1.16, 2.31)</td> <td>10.6 (3.3, 17.9)</td> <td>M^{αβ}</td> </tr> <tr> <td>AUC of reduction in DLQI, Wk 24</td> <td>1124.7 [n = 230]</td> <td>790.7 [n = 236]</td> <td>—</td> <td>334.0 (195.7, 472.3)</td> <td>H</td> </tr> <tr> <td>CFB in HECSI score, Wk 24</td> <td>-69.6 [n = 249]</td> <td>-45.1 [n = 250]</td> <td>—</td> <td>-24.5 (-32.6, -16.4)</td> <td>H</td> </tr> </tbody> </table> <p>The AUC of reduction in DLQI is a measure of the cumulative improvement in the DLQI score. ^α Downgraded for indirectness (investigator- rather than patient-assessed outcome) ^β Downgraded for imprecision (optimal information size not met)</p> <p><i>Duration of an Adequate Therapeutic Trial:</i> 12–16 weeks for delgocitinib and 12 weeks for alitretinoin based on HECSI-90 rates.</p>	Outcome	Delgocitinib Cream N = 250	Alitretinoin N = 253	RR (95% CI)	ARD (95% CI)	Q	CFB in HECSI score, Wk 12	-67.6 [n = 249]	-51.5 [n = 250]	—	-16.1 (-23.3, -8.9)	H	HECSI-90, Wk 12	96/249 (39%)	65/250 (26%)	1.5 (1.14, 1.93)	12.6 (4.3, 20.8)	M ^β	IGA-CHE Treatment Success, Wk 12	68/250 (27%)	42/253 (17%)	1.6 (1.16, 2.31)	10.6 (3.3, 17.9)	M ^{αβ}	AUC of reduction in DLQI, Wk 24	1124.7 [n = 230]	790.7 [n = 236]	—	334.0 (195.7, 472.3)	H	CFB in HECSI score, Wk 24	-69.6 [n = 249]	-45.1 [n = 250]	—	-24.5 (-32.6, -16.4)	H
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Limitations	Predominantly White female study population; non–double-blind study design (although addition of a double-dummy cream vehicle could have increased the treatment effect in the alitretinoin group); lacked assessment of treatment effects on work and activity impairments. Fewer imputations for missing data were made in the delgocitinib cream group than the alitretinoin group because of lower rates of study discontinuation (34/254 [13%] vs 93/259 [36%], respectively) including discontinuation due to adverse events (2/253 [0.8%] vs 24/247 [9.7%], respectively).																																				
Authors' Conclusions	Delgocitinib cream 20 mg/g was superior to alitretinoin in eczema severity and health-related quality of life improvements and safety over a 24-week period in patients with severe CHE																																				
Trial	Efficacy and safety of delgocitinib cream in adults with moderate to severe chronic hand eczema (DELTA 1 and DELTA 2): results from multicentre, randomised, controlled, double-blind, phase 3 trials³																																				
Design	16-week MN DB phase 3 RCTs; randomization was stratified by baseline severity of CHE and region (Europe / North America)																																				
Primary Endpoint	Treatment Success, defined as IGA-CHE score of 0/Clear or 1/Almost Clear with ≥ 2 -step improvement from baseline to Week 16																																				
Population	<p><i>Major Inclusion Criteria:</i> Adults ≥ 18 years; moderate to severe CHE (IGA-CHE score of 3 or 4 on a 5-point scale: 0/Clear to 4/Severe). CHE was defined as hand eczema that has persisted for more than 3 months or returned twice or more within the last 12 months; inadequate response to topical corticosteroids (TCS) within the previous 1 year or medical inadvisability to TCS; Hand Eczema Symptom Diary (HESD) Itch Score (weekly average) of ≥ 4 points</p> <p><i>Major Exclusion Criteria:</i> Previous treatment with systemic or topical JAK inhibitors; topical immunomodulators or corticosteroids in previous 14 days; systemic immunosuppressives or immunomodulators in previous 28 days; concurrent skin diseases on the hands (e.g., tinea manuum); clinically significant infection on the hands (e.g., impetiginized hand eczema); active atopic dermatitis requiring medical treatment on areas other than the hands and feet; active psoriasis on any part of the body; hyperkeratotic hand eczema in combination with a history of psoriasis on any part of the body</p> <p><i>Baseline Characteristics (DELTA 1 DELTA 2):</i> Age, y, 44.0 44.0; male 37% 34%; White 88% 93%; duration of CHE, y, 6.0 5.0; CHE Subtype: Atopic hand eczema 45% 27%; Allergic contact dermatitis 17% 10%; Hyperkeratotic eczema 16% 27%; Irritant contact dermatitis 15% 24%; Vesicular hand eczema (pompholyx/dyshidrotic eczema) 7% 11%.</p>																																				
Interventions	Delgocitinib cream 20 mg/g vs Vehicle cream twice daily for 16 weeks																																				
Co-therapy	Hand emollients were permitted.																																				

Results

DELTA 1 Efficacy Results, Week 16

Outcome	Delgocitinib Cream, n/N (%)	Vehicle Cream, n/N (%)	RR (95% CI)	ARD (95% CI)	Q
IGA-CHE Treatment Success	64/325 (19.7)	16/162 (9.9)	2.0 (1.19, 3.22)	9.8 (3.6, 16.1)	L ^{ab}
HESD Itch Reduction ≥ 4	152/323 (47.1)	37/161 (23.0)	2.0 (1.51, 2.78)	24.1 (15.5, 32.6)	M ^β
DLQI-4	227/305 (74.4)	74/148 (50.0)	1.5 (1.25, 1.77)	24.5 (15.0, 33.9)	H

DELTA 2 Efficacy Results, Week 16

Outcome	Delgocitinib Cream, n/N (%)	Vehicle Cream, n/N (%)	RR (95% CI)	ARD (95% CI)	Q
IGA-CHE Treatment Success	91/313 (29.1)	11/159 (6.9)	4.2 (2.32, 7.63)	22.2 (15.8, 28.5)	L ^{ab}
HESD Itch Reduction ≥ 4	146/309 (47.2)	31/156 (19.9)	2.4 (1.70, 3.33)	27.4 (19.0, 35.8)	M ^β
DLQI-4	216/299 (72.2)	70/153 (45.8)	1.6 (1.31, 1.90)	26.4 (17.0, 35.9)	H

- Other outcomes for which delgocitinib was statistically superior to cream vehicle: HESD pain reduction ≥ 4 points from baseline to Weeks 4, 8, and 16; Hand Eczema Severity Index (HECSI) reduction of at least 90% or 75%; change from baseline in Hand Eczema Impact Scale (HEIS) score and HEIS Proximal Daily Activity Limitations (PDAL) score.
- *Subgroup Analyses:* In DELTA 1, the treatment effect was larger in males than females (ARD 17.8% vs 5.4%). In DELTA 2, the treatment effect was similar by sex (20.6% vs 23.2%, respectively). The effects were similar by age group (< 65/≥ 65 years).

Limitations

Predominantly White female study population; short study duration; co-use of emollients was not reported.

Authors' Conclusions

Delgocitinib cream 2% was superior to cream vehicle in terms of IGA-CHE treatment success, and the findings between the two DELTA studies consistently showed that topical delgocitinib therapy was efficacious and well tolerated with no safety concerns.

Trial

Long-term safety and efficacy of delgocitinib cream for up to 52 weeks in adults with Chronic Hand Eczema: Results of the phase 3 open-label extension DELTA 3 trial following the DELTA 1 and 2 trials⁴

Design

36-week, phase 3, MN open-label long-term extension trial

Primary Endpoint

Number of treatment-emergent adverse events (TEAEs)

Population

Adults with CHE who completed either DELTA 1 or DELTA 2

Baseline Characteristics

- Age 45 y; male 36%; White 91.4%; North America (Canada) 20.2%; duration of CHE 5.0 y.
- IGA-CHE of Mild | Moderate | Severe: 43.1% | 30.3% | 6.6%.
- Median weekly average HESD Itch score: 3.4.

Interventions

Delgocitinib 20 mg/g every 12 hours as needed, when IGA-CHE score ≥ 2 (stopped when IGA-CHE score was 0/Clear or 1/Almost Clear).

Results

IGA-CHE 0/1 Responder Rates at Week 0 | Week 36 were 24.6% | 30.0% in the previous delgocitinib group (N = 560) and 9.1% | 29.5% in the previous cream vehicle group (N = 241).

Limitations

Non-US trial; open-label; predominantly White female study population; co-use of emollients was not reported.

Authors' Conclusions

The results support the safety and benefit of long-term, as-needed treatment with delgocitinib cream for up to 52 weeks in patients with moderate to severe CHE.

Other Trials of Potential Interest

The pan-JAK inhibitor delgocitinib in a cream formulation demonstrates dose response in chronic hand eczema in a 16-week randomized phase IIb trial⁵

Treatment with delgocitinib cream improves itch, pain and other signs and symptoms of chronic hand eczema: Results from the Hand Eczema Symptom Diary in a phase IIb randomized clinical trial⁶

Health-Related Quality of Life in Chronic Hand Eczema in a Phase 2b Trial of Delgocitinib Cream⁷

Efficacy and safety of topical delgocitinib in patients with chronic hand eczema: data from a randomized, double-blind, vehicle-controlled phase IIa study⁸

Systemic exposure and bioavailability of delgocitinib cream in adults with moderate to severe Chronic Hand Eczema⁹

SAFETY CONSIDERATIONS

Boxed Warnings	None
Contraindications	None
Other Warnings	Serious infections; nonmelanoma skin cancers (NMSC); immunizations; potential risks related to JAK inhibition: mortality, major adverse cardiovascular events, thrombosis, malignancies (excluding NMSC).
Top 5 AEs	Application site pain, paresthesia, pruritus, erythema, bacterial skin infections
Drug Interactions	Not studied.
Pregnancy	<i>Humans:</i> Insufficient data. <i>Animals:</i> Animal studies showed post-implantation loss but no embryofetal toxicity in rabbits, and decreases in fetal weight and skeletal variations in rats. No adverse developmental effects were seen at maximum recommended human doses.
Lactation	<i>Humans:</i> Insufficient data. Advise breastfeeding women to avoid direct contact with the nipple and surrounding area immediately after applying delgocitinib to the hands and/or wrists. <i>Animals:</i> Drug detected in rat milk, suggesting that drug will likely be present in human milk. Weigh potential risks vs benefits.

Trial Safety Results**24-Week DELTA FORCE Safety Results**

Adverse Event (AE)	Delgocitinib 2% Cream N = 253; PYO = 120.9		Alitretinoin N = 247; PYO = 104.0		Rate Ratio (95% CI)	ARD (95% CI)
	n (%)	Event Rate	n (%)	Event Rate		
Death	0	0	0	0	NA	0.0 (-1.5, 1.5)
Serious AE	5 (2)	4.1	12 (5)	11.5	0.36 (0.13, 1.02)	-2.9 (-6.5, 0.4)
Discontinuation Due to AE	3 (1)	3.3	25 (10)	42.3	0.08 (0.03, 0.22)	-8.9 (-13.4, -5.1)
Any AE	125 (49)	231.5	188 (76)	596.1	0.39 (0.34, 0.45)	-26.7 (-34.5, -18.3)
Eczema herpeticum	0	0	0	0	NA	0.0 (-1.5, 1.5)

Event rate = number of events per patient year of observation (PYO) x 100

- Compared with alitretinoin, delgocitinib cream had a lower risk of urinary tract infection, skin erythema, headache, nausea, diarrhea, dry lips, hypercholesterolemia, and dry eye.

16-Week DELTA 1 Safety Results

Adverse Event	Delgocitinib 2% Cream N = 325; PYO = 100.85		Vehicle N = 162; PYO = 48.55		Rate Ratio (95% CI)	ARD (95% CI)
	n (%)	Event Rate	n (%)	Event Rate		
Death	0	—	0	—	—	0.0 (-2.3, 1.2)
Serious AE	6 (2)	6.9	3 (2%)	8.2	0.8 (0.2, 2.9)	0.0 (-3.6, 2.4)
Discontinuation Due to AE	2 (1)	2.0	6 (4)	14.4	0.1 (0.0, 0.7)	-3.1 (-7.3, -0.5)
Any AE	147 (45)	305.4	82 (51)	331.6	0.9 (0.8, 1.1)	-5.4 (-14.7, 4.0)

16-Week DELTA 2 Safety Results

Adverse Event	Delgocitinib 2% Cream N = 313; PYO = 95.87		Vehicle N = 159; PYO = 45.36		Rate Ratio (95% CI)	ARD (95% CI)
	n (%)	Event Rate	n (%)	Event Rate		
Death	0	—	0	—	—	0.0 (-2.4, 1.2)
Serious AE	5 (2)	5.2	3 (2)	8.8	0.6 (0.2, 2.2)	-0.3 (-3.9, 2.1)
Discontinuation Due to AE	1 (≤1)	1.0	5 (3)	11.0	0.1 (0.0, 0.8)	-2.8 (-6.8, -0.5)
Any AE	143 (46)	280.6	71 (45)	319.7	0.9 (0.7, 1.1)	1.0 (-8.4, 10.4)

36-Week DELTA 3 Safety Results (Total 52 Weeks)

Adverse Event	Delgocitinib 2% Cream N = 801; PYO = 535.65	
	n (%)	Event Rate
Death	2 (0.4)	0.53
Serious AE	27 (3.4)	6.72
Discontinuation Due to AE	7 (0.9)	1.49
Any AE	495 (61.8)	231.12

Pharmacokinetics	<ul style="list-style-type: none"> Minimal systemic exposure; bioavailability 0.6% vs oral administration No drug accumulation following twice-daily application for 14 days.
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OTHER CONSIDERATIONS

FDA Review¹⁰	<ul style="list-style-type: none"> A Boxed Warning for potential adverse reactions related to JAK inhibition was not considered necessary because the risk was considered low. Delgocitinib cream would be applied to < 5% of body area of patients with CHE and had a low systemic exposure. Furthermore, major adverse cardiovascular events, malignancy, and thrombosis were not observed during the clinical trials, and these events are dose-dependent. However, labeling about the potential risks were included in the Warnings and Precautions since the safety database was of inadequate size and duration to exclude potential adverse reactions associated with other JAK inhibitors for inflammatory disorders. Postmarketing safety surveillance data for up to 4 years from use of delgocitinib cream or ointment outside the US have not identified any safety concerns but was limited by a lack of data on the number of patients exposed and duration of treatment. The most common reports were application site adverse reactions, mostly mild. Eczema herpeticum (EH, a potentially life-threatening systemic herpes simplex viral infection) was reported in 2.2% of cases. There is biological plausibility for an association between delgocitinib cream and EH, and a causal relationship to delgocitinib cannot be ruled out.
ICER Review	No review found.
NICE Review	Review in development.

THERAPEUTIC ALTERNATIVES AND THEIR PLACE IN THERAPY

ESCD Guidelines on Hand Eczema (2021)¹¹	<p>Recommend moderate and potent topical corticosteroids for moderate hand eczema or severe or very severe hand eczema.</p> <p>Recommend topical corticosteroids as short-term first-line treatment. QOE = Moderate. GOR = A.</p> <p>State that long-term intermittent use of topical corticosteroids as maintenance therapy may be considered (evidence for efficacy is limited). QOE = Low. GOR = 0.</p> <p>Suggest tacrolimus ointment for short-term treatment. QOE = Moderate. GOR = B.</p> <p>Suggest tacrolimus ointment for patients either refractory to topical corticosteroid or when fear of side effects of topical corticosteroid exist, or in the chronic stage. Off-label except for atopic hand eczema.</p> <p>Suggest tacrolimus ointment for almost-clear hand eczema or moderate hand eczema.</p> <p>Do not mention tapinarof.</p>
International Eczema Council (IEC) Guidelines on CHE¹²	Did not address treatment of CHE.

TOPICAL THERAPY FOR MODERATE–SEVERE ATOPIC DERMATITIS	VANF	CFU	ISSUES FOR CONSIDERATION
<i>Super-high Potency (Group 1) Corticosteroids</i>			
Betamethasone dipropionate augmented cream 0.05%	Yes	No	
Betamethasone dipropionate oint 0.05%			
Clobetasol propionate cream 0.025%			
<hr/>			
Amcinonide oint 0.1%	No	No	
Betamethasone dipropionate augmented gel 0.05%			
Desoximetasone cream, oint 0.25%			
Diflorasone diacetate oint, cream emollient 0.05%			
Halcinonide cream, oint 0.1%			
Halobetasol propionate lotion 0.01%			
<i>High-potency (Group 2) Corticosteroids</i>			
Betamethasone dipropionate augmented cream 0.05%	Yes	No	
Betamethasone dipropionate oint 0.05%			
Clobetasol propionate cream 0.025%			
<hr/>			
Amcinonide oint 0.1%	No	No	
Betamethasone dipropionate augmented lotion 0.05%			
Desoximetasone cream, oint 0.25%			
Diflorasone diacetate oint, cream emollient 0.05%			
Halcinonide cream, oint 0.1%			
Halobetasol propionate lotion 0.01%			
<i>High-potency (Group 3) Corticosteroids</i>			
Betamethasone dipropionate cream 0.05%	Yes	No	
Betamethasone valerate oint 0.1%			
Triamcinolone acetonide cream, oint 0.5%			
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Amcinonide cream 0.1%	No	No	
Betamethasone valerate foam/aerosol 0.12%			
Desoximetasone cream, oint 0.05%			
Diflorasone diacetate cream 0.05%			
Fluocinonide cream, aqueous emollient 0.05%			
Fluticasone propionate oint 0.005%			
Mometasone furoate oint 0.1%			
<i>Medium-potency (Group 4) Corticosteroids</i>			
Triamcinolone acetonide cream, oint 0.1%	Yes	No	Triamcinolone oint 0.1% twice daily (medium potency) was shown to be similar in efficacy to mometasone furoate oint 0.1% (high potency, group 3) for allergic contact hand eczema at 12 wks.
Clocortolone pivalate cream 0.1%	No	No	
Flurandrenolide oint 0.05%			
Fluticasone propionate cream 0.05%			
Hydrocortisone valerate oint 0.2%			
Mometasone furoate cream, lotion 0.1%			
<i>Calcineurin Inhibitor</i>			
Tacrolimus oint 0.1%	Yes	No	Used off label for allergic contact dermatitis. Pimecrolimus cream 1% is indicated for mild–moderate AD but has been shown to be ineffective for mild–moderate CHE. ¹³
<i>Aryl Hydrocarbon Receptor Agonist</i>			
Tapinarof cream 1%	No	Yes, after TCS and TCI for moderate–severe atopic dermatitis	Indicated for atopic dermatitis; therefore, it may be considered for moderate-to-severe <i>atopic</i> CHE. A literature search found no RCTs evaluating tapinarof cream specifically for CHE.

POTENTIAL PLACE IN THERAPY OF DELGOCITINIB CREAM

Background	Chronic hand eczema (CHE) is the most common occupational skin disease, and it can have significant negative consequences on work, income, and psychosocial function. CHE has etiologic subtypes (irritant contact dermatitis, allergic contact dermatitis, atopic hand eczema, protein contact dermatitis/contact urticaria) and clinical subtypes (hyperkeratotic, acute recurrent vesicular, nummular, and pulpitis). ¹¹ Allergic contact dermatitis occurs more often in men than women, and hyperkeratotic hand eczema is the most common clinical subtype in men. There is no ICD-10 diagnostic code for CHE; therefore, the prevalence of CHE in VHA is unknown. Delgocitinib cream is the first product FDA-approved specifically for the treatment of CHE.
Summary of Evidence	<p>CHE was defined as hand eczema that persisted for > 3 months or returned twice or more in the previous 12 months.</p> <p>The single-blind, active-controlled DELTA FORCE trial showed that topical delgocitinib cream was superior to oral alitretinoin (small effects) in improving eczema severity, achieving clear/almost clear skin, and improving dermatology-related quality of life, and had a better safety profile, in patients with severe CHE who had an inadequate response or medical inadvisability to topical corticosteroids. The frequency of emollient use, which may have an additive therapeutic effect, was not reported.</p> <p>The DELTA 1 and DELTA 2 vehicle-controlled RCTs showed that delgocitinib cream improved CHE severity, pruritus, pain, quality of life, and impact on daily activities in patients with moderate to severe CHE who had an inadequate response or medical inadvisability to topical corticosteroids. The effects of any co-use of emollients on treatment differences is unknown.</p> <p>The observational DELTA 3 long-term extension study showed that as-needed delgocitinib cream therapy maintained control of CHE with an acceptable safety profile for up to Week 52.</p> <p>Evidence gaps include the lack of comparative efficacy studies of delgocitinib cream vs other topical therapies, long-term studies beyond 52 weeks including evaluations of the risk of eczema herpeticum and its potential causal relationship with delgocitinib, and studies on real-world experience.</p>
Potential Treatment Sequencing	<ol style="list-style-type: none"> 1. Moderate-to-high-potency topical corticosteroid 2. Tacrolimus ointment 0.1% 3. Tapinarof cream 1% if the CHE is the atopic subtype 4. Delgocitinib cream 2%

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Contact person: Francine Goodman, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)

References

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