

Texas Prior Authorization Program  
Clinical Criteria

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## Drug/Drug Class

# Topical Immunomodulators

## Clinical Criteria Information Included in this Document

Zoryve (Roflumilast) 0.3% and 0.15% cream

- [Drugs requiring prior authorization](#): the list of drugs requiring prior authorization for this clinical criteria
- [Prior authorization criteria logic](#): a description of how the prior authorization request will be evaluated against the clinical criteria rules
- [Logic diagram](#): a visual depiction of the clinical criteria logic
- [Supporting tables](#): a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- [References](#): clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

Zoryve (Roflumilast) 0.3% foam

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## Revision Notes

Initial publication and presentation to the DUR Board



**Zoryve (Roflumilast) cream**  
**Drugs Requiring Prior Authorization**

*The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](https://TxVendorDrug.com/formulary/formulary-search).*

Drugs Requiring Prior Authorization	
Label Name	GCN
ZORYVE 0.15% CREAM	55978
ZORYVE 0.3% CREAM	52657

**Zoryve (Roflumilast) cream****Clinical Criteria Logic**Initial Request:

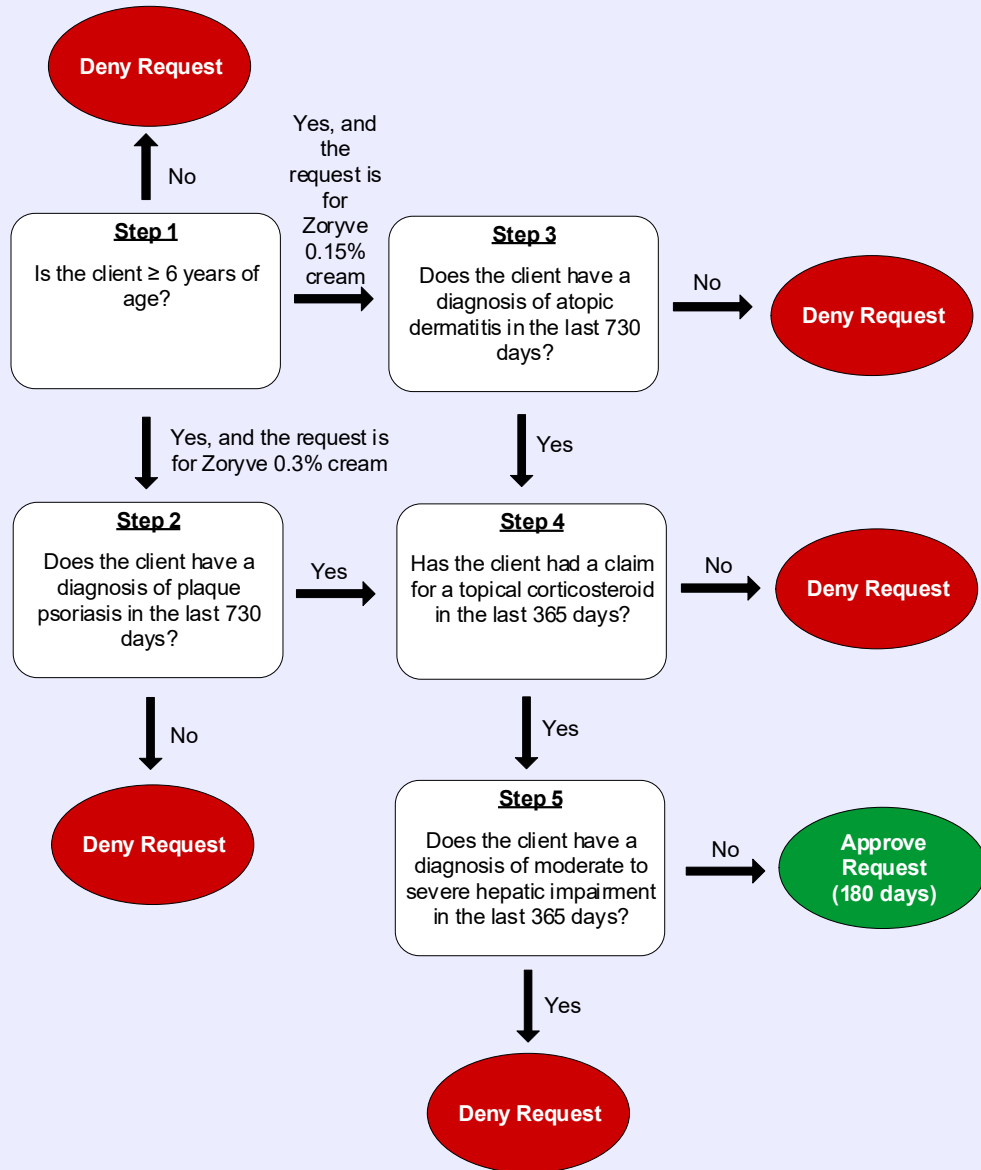
1. Is the client greater than or equal to ( $\geq$ ) 6 years of age?
  - Yes, and the request is for Zoryve 0.3% cream - Go to #2
  - Yes, and the request is for Zoryve 0.15% cream - Go to #3
  - No - Deny
2. Does the client have a diagnosis of [plaque psoriasis](#) in the last 730 days?
  - Yes - Go to #4
  - No - Deny
3. Does the client have a diagnosis of [atopic dermatitis](#) in the last 730 days?
  - Yes - Go to #4
  - No - Deny
4. Has the client had a claim for a [topical corticosteroid](#) in the last 365 days?
  - Yes - Go to #5
  - No - Deny
5. Does the client have a diagnosis of [moderate to severe hepatic impairment](#) in the last 365 days?
  - Yes - Deny
  - No - Approve – 180 days

Renewal Request:

1. Does the client have a prior PA in the last 365 days?
  - Yes - Go to #2
  - No - Deny
2. Does the client have a diagnosis of [moderate to severe hepatic impairment](#) in the last 365 days?
  - Yes - Deny
  - No - Approve – 365 days

**PAYPRESS™** **Zoryve (Roflumilast) cream**  
**Clinical Criteria Logic Diagram**

Initial Requests:

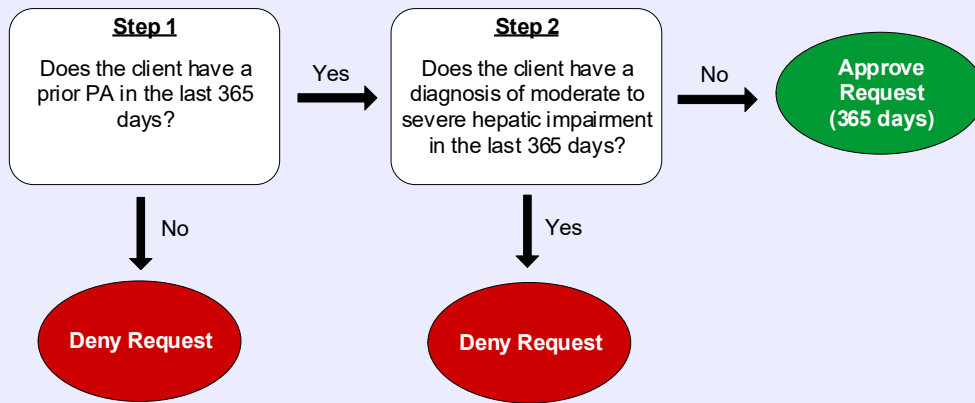




# Zoryve (Roflumilast) cream

## Clinical Criteria Logic Diagram

Renewal Requests:





**Zoryve (Roflumilast) foam**  
**Drugs Requiring Prior Authorization**

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Drugs Requiring Prior Authorization	
Label Name	GCN
ZORYVE 0.3% FOAM	55119

**Zoryve (Roflumilast) foam****Clinical Criteria Logic**Initial Request:

1. Is the client greater than or equal to ( $\geq$ ) 9 years of age?  
 Yes - Go to #2  
 No - Deny
2. Does the client have a diagnosis of [seborrheic dermatitis](#) in the last 730 days?  
 Yes - Go to #3  
 No - Deny
3. Has the client had a claim for a [topical corticosteroid](#) in the last 365 days?  
 Yes - Go to #4  
 No - Deny
4. Does the client have a diagnosis of [moderate to severe hepatic impairment](#) in the last 365 days?  
 Yes - Deny  
 No - Approve – 180 days

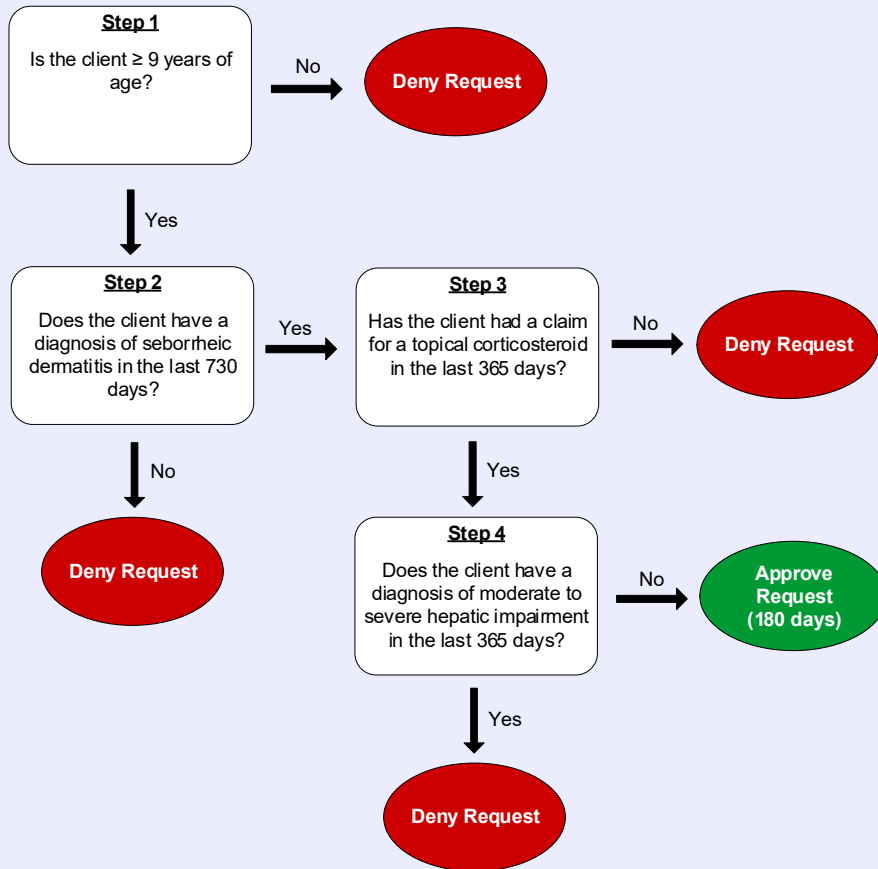
Renewal Request:

1. Does the client have a prior PA in the last 365 days?  
 Yes - Go to #2  
 No - Deny
2. Does the client have a diagnosis of [moderate to severe hepatic impairment](#) in the last 365 days?  
 Yes - Deny  
 No - Approve – 365 days

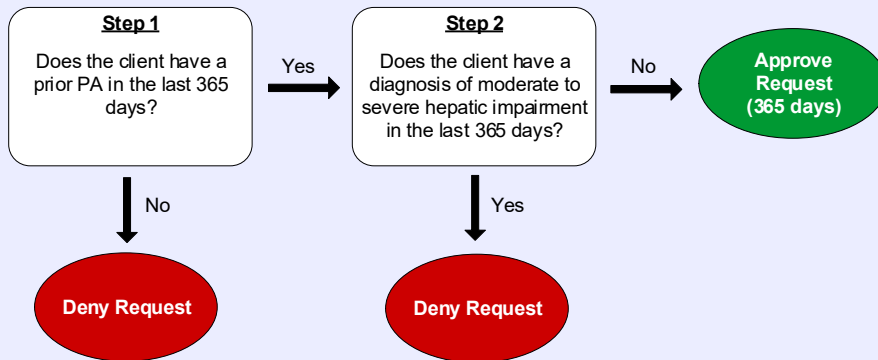


**PAYPRESS™** **Zoryve (Roflumilast) foam**  
**Clinical Criteria Logic Diagram**

Initial Requests:



Renewal Requests:





## Zoryve (Roflumilast)

### Clinical Criteria Supporting Tables

Plaque Psoriasis	
ICD-10 Code	Description
L400	PSORIASIS VULGARIS
L401	GENERALIZED PUSTULAR PSORIASIS
L402	ACRODERMATITIS CONTINUA
L403	PUSTULOSIS PALMARIS ET PLANTARIS
L404	GUTTATE PSORIASIS
L408	OTHER PSORIASIS
L409	PSORIASIS, UNSPECIFIED

Atopic Dermatitis	
ICD-10 Code	Description
L200	BESNIER'S PRURIGO
L2081	ATOPIC NEURODERMATITIS
L2082	FLEXURAL ECZEMA
L2084	INTRINSIC (ALLERGIC) ECZEMA
L2089	OTHER ATOPIC DERMATITIS
L209	ATOPIC DERMATITIS, UNSPECIFIED

Seborrheic Dermatitis	
ICD-10 Code	Description
L210	SEBORRHEIC CAPITIS
L218	OTHER SEBORRHEIC DERMATITIS
L219	SEBORRHEIC DERMATITIS, UNSPECIFIED

Topical Corticosteroids	
Label Name	GCN
ALCLOMETASONE DIPRO 0.05% CRM	33710
ALCLOMETASONE DIPR 0.05% OINT	33730
AMCINONIDE 0.1% CREAM	31490
AMCINONIDE 0.1% LOTION	31560
APEXICON E 0.05% CREAM	67730
BETAMETHASONE DP 0.05% CRM	31060
BETAMETHASONE DP 0.05% LOT	31080
BETAMETHASONE DP 0.05% OINT	31070
BETAMETHASONE DP AUG 0.05% CRM	31890
BETAMETHASONE DP AUG 0.05% GEL	32091
BETAMETHASONE DP AUG 0.05% LOT	30980
BETAMETHASONE DP AUG 0.05% OIN	31910
BETAMETHASONE VA 0.1% CREAM	31101
BETAMETHASONE VA 0.1% LOTION	31120
BETAMETHASONE VALER 0.1% OINTM	31110
BETAMETHASONE VALER 0.12% FOAM	32052
BRYHALI 0.01% LOTION	45728
CLOBETASOL 0.05% CREAM	32140
CLOBETASOL 0.05% GEL	15892
CLOBETASOL 0.05% OINTMENT	32130
CLOBETASOL 0.05% SOLUTION	15891
CLOBETASOL 0.05% TOPICAL LOTN	34040
CLOBETASOL EMOLLIENT 0.05% CRM	34141
CLOBETASOL EMULSION 0.05% FOAM	97649
CLOBETASOL PROP 0.05% FOAM	89743

Topical Corticosteroids	
Label Name	GCN
CLOBETASOL PROP 0.05% SPRAY	25909
CLOBEX 0.05% SPRAY	25909
CLOBEX 0.05% TOPICAL LOTION	34040
CLOCORTOLONE PIVALATE 0.1% CRM	31190
CLODERM 0.1% CREAM	31190
CORDRAN 4 MCG/SQ CM TAPE	31300
CUTIVATE 0.05% LOTION	24717
DERMA-SMOOTHIE-FS BODY OIL	85080
DERMA-SMOOTHIE-FS SCALP OIL	24484
DESONATE 0.05% GEL	97930
DESONIDE 0.05% CREAM	31425
DESONIDE 0.05% LOTION	48971
DESONIDE 0.05% OINTMENT	31430
DESOXIMETASONE 0.05% CREAM	31180
DESOXIMETASONE 0.25% CREAM	31181
DESOXIMETASONE 0.05% GEL	06120
DESOXIMETASONE 0.25% OINTMENT	30800
DESOXIMETASONE 0.25% SPRAY	34545
DIFLORASONE 0.05% CREAM	31470
DIFLORASONE 0.05% OINTMENT	31480
DIPROLENE 0.05% OINTMENT	31910
FLUOCINOLONE 0.01% CREAM	31342
FLUOCINOLONE 0.025% CREAM	31344
FLUOCINONIDE 0.05% CREAM	31390
FLUOCINONIDE 0.05% GEL	31380

Topical Corticosteroids	
Label Name	GCN
FLUOCINOLONE 0.025% OINT	31351
FLUOCINONIDE 0.05% OINTMENT	31400
FLUOCINOLONE 0.01% BODY OIL	85080
FLUOCINOLONE 0.01% SOLUTION	31360
FLUOCINONIDE 0.05% SOLUTION	31401
FLUOCINONIDE 0.1% CREAM	24306
FLUOCINONIDE-E 0.05% CREAM	54650
FLURANDRENOLIDE 0.05% CREAM	28711
FLURANDRENOLIDE 0.05% LOTION	31310
FLUTICASONE PROP 0.05% CREAM	43951
FLUTICASONE 0.05% LOTION	24717
FLUTICASONE PROP 0.005% OINT	48641
HALCINONIDE 0.1% CREAM	31441
HALOBETASOL PROP 0.05% CREAM	31251
HALOBETASOL PROP 0.05% OINTMNT	31211
HALOG 0.1% CREAM	31441
HALOG 0.1% OINTMENT	31451
HYDROCORTISONE-ALOE 1% CREAM	92421
HYDROCORTISONE 1% CREAM	30942
HYDROCORTISONE 2.5% CREAM	30943
HYDROCORTISONE 2.5% LOTION	30975
HYDROCORTISONE 0.5% OINTMENT	30950
HYDROCORTISONE 1% CREAM	28851
HYDROCORTISONE 1% OINTMENT	30951
HYDROCORTISONE 2.5% OINTMENT	30952

Topical Corticosteroids	
Label Name	GCN
HYDROCORTISONE 0.1% SOLN	48811
HYDROCORTISONE BUTY 0.1% CREAM	30880
HYDROCORT BUTY 0.1% LIPO CREAM	20706
HYDROCORTISONE BUTYR 0.1% LOTN	62480
HYDROCORTISONE BUTYR 0.1% OINT	30885
HYDROCORTISONE VAL 0.2% CREAM	30890
HYDROCORTISONE VAL 0.2% OINTMT	06040
LEXETTE 0.05% FOAM	45667
LUXIQ 0.12% FOAM	32052
MOMETASONE FUROATE 0.1% CREAM	45850
MOMETASONE FUROATE 0.1% OINT	45930
MOMETASONE FUROATE 0.1% SOLN	06034
OLUX 0.05% FOAM	89743
OLUX-E 0.05% FOAM	97649
PANDEL 0.1% CREAM	50550
PREDNICARBATE 0.1% CREAM	37181
PREDNICARBATE 0.1% OINTMENT	37182
TEMOVATE 0.05% CREAM	32140
TEMOVATE 0.05% OINTMENT	32130
TEXACORT 2.5% SOLUTION	09181
TOPICORT 0.05% GEL	06120
TOPICORT 0.05% OINTMENT	11403
TOPICORT 0.25% CREAM	31181
TOPICORT 0.25% OINTMENT	30800
TOPICORT 0.25% SPRAY	34545

Topical Corticosteroids	
Label Name	GCN
TOPICORT LP 0.05% CREAM	31180
TRIAMCINOLONE 0.025% CREAM	31231
TRIAMCINOLONE 0.05% OINTMENT	31244
TRIAMCINOLONE 0.1% CREAM	31232
TRIAMCINOLONE 0.5% CREAM	31233
TRIAMCINOLONE 0.025% LOTION	31260
TRIAMCINOLONE 0.1% LOTION	31261
TRIAMCINOLONE 0.025% OINT	31241
TRIAMCINOLONE 0.1% OINTMENT	31242
TRIAMCINOLONE 0.5% OINTMENT	31244
TRIANEX 0.05% OINTMENT	31243
ULTRAVATE 0.05% CREAM	31251
ULTRAVATE X CREAM COMBO PACK	32631
ULTRAVATE X OINTMENT COMBO PACK	32630
VANOS 0.1% CREAM	24306

Moderate to Severe Hepatic Impairment	
ICD-10 Code	Description
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA

Moderate to Severe Hepatic Impairment	
ICD-10 Code	Description
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS



Moderate to Severe Hepatic Impairment	
ICD-10 Code	Description
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS

Moderate to Severe Hepatic Impairment	
ICD-10 Code	Description
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE



## Zoryve (Roflumilast)

### Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on October 25, 2024.
2. Micromedex [online database]. Available at [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed on October 25, 2024.
3. Zoryve Cream Prescribing Information. Westlake Village, CA. Arcutis Biotherapeutics, Inc. July 2024.
4. Zoryve Foam Prescribing Information. Westlake Village, CA. Arcutis Biotherapeutics, Inc. December 2023.

**Zoryve (Roflumilast)****Publication History**

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the [Revision Notes](#) on the first page of this document.

Publication Date	Notes
10/25/2024	<ul style="list-style-type: none"><li>Initial Publication and Presentation to the DUR Board</li></ul>