

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class

Hereditary Angioedema (HAE)

Clinical Criteria Information Included in this Document

Agents for the treatment of HAE

- **Drugs requiring clinical prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Clinical 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)
- **References:** clinical publications and sources relevant to this clinical criteria

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

Revision Notes

Updated HAE Agents criteria logic for presentation to the DUR Board

- Added criteria for Orladeyo (new agent)
- Added check for P-gp inducers (drug interaction) for Ruconest and Orladeyo
- Added check for agents that may exacerbate HAE
- Added check for duplicate therapy with HAE prophylactic agents



HAE Agents

Drugs Requiring Clinical 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.

Medication for HAE Prophylaxis	
Label Name	GCN
BERINERT 500 UNIT KIT	31159
CINRYZE 500 UNIT VIAL	10495
FIRAZYR 30 MG/3 ML SYRINGE	14778
HAEGARDA 2,000 UNIT VIAL	37478
HAEGARDA 3,000 UNIT VIAL	43356
KALBITOR 10 MG/ML VIAL	28088
ORLADEYO 110 MG CAPSULE	48948
ORLADEYO 150 MG CAPSULE	48947
RUCONEST 2100 UNIT VIAL	30182
TAKHZYRO 300 MG/2 ML VIAL	45184



HAE Agents

Clinical Criteria Logic

1. Is the client \geq 5 years of age?
 - Yes – And request is for Berinert, go to #7
 - Yes – And request is for another agent, go to #2
 - No – Deny

2. Is the client \geq 6 years of age?
 - Yes – And request is for Cinryze or Haegarda, go to #7
 - Yes – And request is for another agent, go to #3
 - No – Deny

3. Is the client \geq 12 years of age?
 - Yes – And the request is for Kalbitor or Takhzyro, go to #7
 - Yes – And the request is for Orladeyo, go to #6
 - Yes – And the request is for another agent, go to #4
 - No – Deny

4. Is the client \geq 13 years of age?
 - Yes – And request is for Ruconest, go to #6
 - Yes – And request is for another agent, go to #5
 - No – Deny

5. Is the client \geq 18 years of age?
 - Yes – And request is for Firazyr, go to #7
 - No - Deny

6. Does the client have a claim for a **P-gp inducer** in the last 60 days?
 - Yes – Deny
 - No – Go to #7

7. Does the client have 2 claims for the requested agent in the last 180 days?
 - Yes – Go to #9
 - No – Go to #8

8. Does the client have a **diagnosis of hereditary angioedema** in the last 730 days?
 - Yes – Go to #9
 - No – Deny

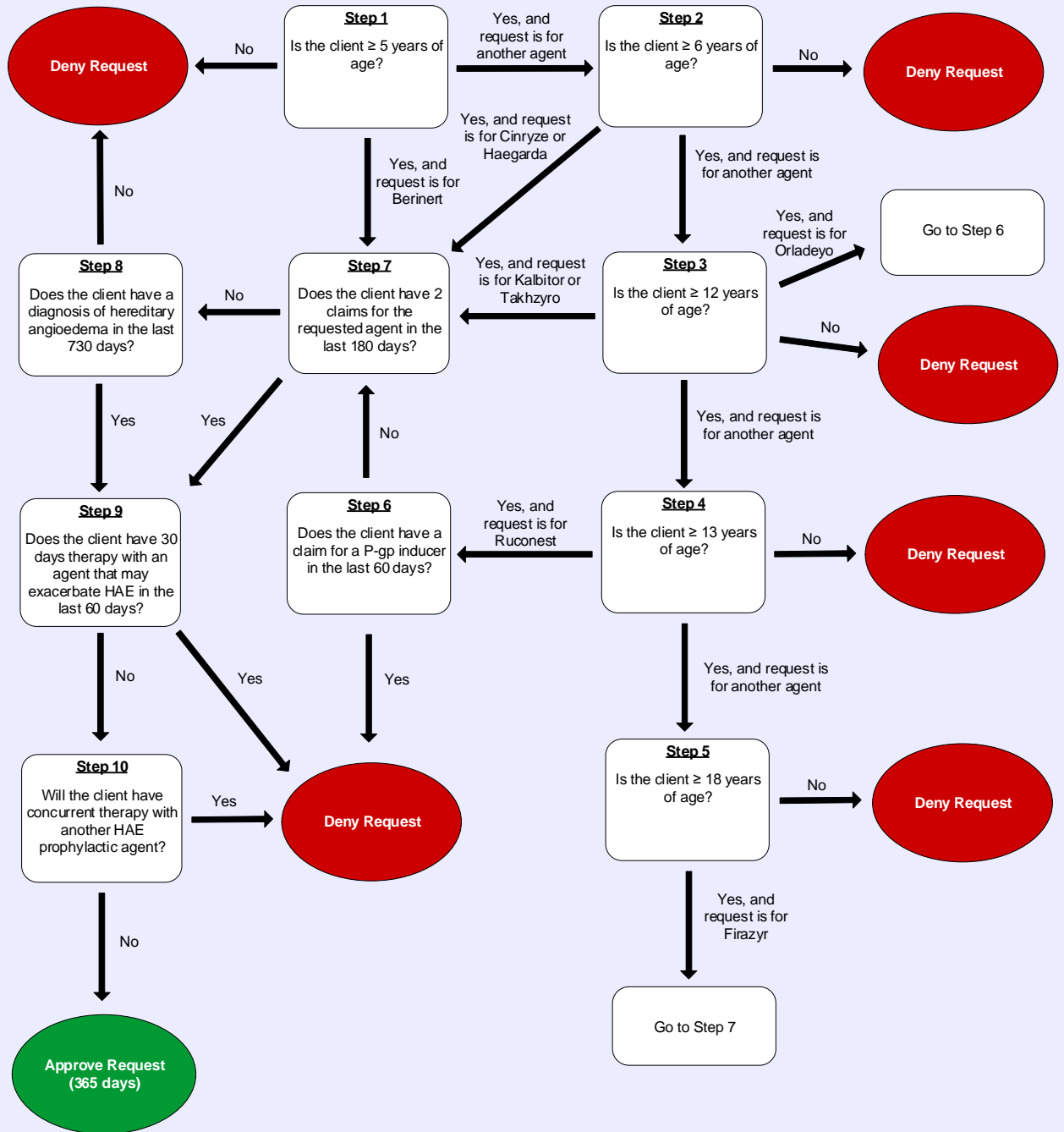
9. Does the client have 30 days therapy with an **agent that may exacerbate HAE** in the last 60 days?
 - Yes – Deny
 - No – Go to #10

10. Will client have concurrent therapy with another HAE prophylactic agent?
 - Yes – Deny
 - No – Approve (365 days)



HAE Agents

Clinical Criteria Logic Diagram





HAE Agents

Clinical Criteria Supporting Tables

Step 6 (therapy with a P-gp inducer)	
Required claims: 1	
Look back timeframe: 60 days	
Label Name	GCN
CARBAMAZEPINE 100 MG TAB CHEW	17460
CARBAMAZEPINE 100 MG/5 ML SUSP	47500
CARBAMAZEPINE 200 MG TABLET	17450
CARBAMAZEPINE ER 100 MG CAP	23934
CARBAMAZEPINE ER 100 MG TAB	27820
CARBAMAZEPINE ER 200 MG CAP	23932
CARBAMAZEPINE ER 200 MG TABLET	27821
CARBAMAZEPINE ER 300 MG CAP	23933
CARBAMAZEPINE ER 400 MG TABLET	27822
CARBATROL ER 100 MG CAPSULE	23934
CARBATROL ER 200 MG CAPSULE	23932
CARBATROL ER 300 MG CAPSULE	23933
DILANTIN 100 MG CAPSULE	17700
DILANTIN 125 MG/5 ML SUSP	17241
DILANTIN 30 MG CAPSULE	17701
DILANTIN 50 MG INFATAB	17250
EPITOL 200 MG TABLET	17450
EQUETRO 100 MG CAPSULE	13781
EQUETRO 200 MG CAPSULE	13805
EQUETRO 300 MG CAPSULE	13818
PHENOBARBITAL 100 MG TABLET	12975
PHENOBARBITAL 130 MG/ML VIAL	12892
PHENOBARBITAL 15 MG TABLET	12971
PHENOBARBITAL 16.2 MG TABLET	97706
PHENOBARBITAL 20 MG/5 ML ELIX	12956
PHENOBARBITAL 30 MG TABLET	12973
PHENOBARBITAL 32.4 MG TABLET	97965
PHENOBARBITAL 60 MG TABLET	12972
PHENOBARBITAL 64.8 MG TABLET	97966
PHENOBARBITAL 65 MG/ML VIAL	12894

Step 6 (therapy with a P-gp inducer)	
Required claims: 1	
Look back timeframe: 60 days	
PHENOBARBITAL 97.2 MG TABLET	97967
PHENYTEK 200 MG CAPSULE	15038
PHENYTEK 300 MG CAPSULE	15037
PHENYTOIN 125 MG/5 ML SUSP	17241
PHENYTOIN 50 MG TABLET CHEW	17250
PHENYTOIN 50 MG/ML VIAL	17200
PHENYTOIN SOD EXT 100 MG CAP	17700
PHENYTOIN SOD EXT 200 MG CAP	15038
PHENYTOIN SOD EXT 300 MG CAP	15037
RIFADIN 150 MG CAPSULE	41260
RIFADIN 300 MG CAPSULE	41261
RIFADIN IV 600 MG VIAL	41470
RIFAMATE CAPSULE	89800
RIFAMPIN 150 MG CAPSULE	41260
RIFAMPIN 300 MG CAPSULE	41261
RIFAMPIN IV 600 MG VIAL	41470
RIFATER TABLET	14142
TEGRETOL 100 MG/5 ML SUSP	47500
TEGRETOL 200 MG TABLET	17450
TEGRETOL XR 100 MG TABLET	27820
TEGRETOL XR 200 MG TABLET	27821
TEGRETOL XR 400 MG TABLET	27822

Step 8 (diagnosis of hereditary angioedema)	
Required quantity: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
D841	DEFECTS IN THE COMPLEMENT SYSTEM

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
ACCUPRIL 10 MG TABLET	27570
ACCUPRIL 20 MG TABLET	27571

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
ACCUPRIL 40 MG TABLET	27573
ACCUPRIL 5 MG TABLET	27572
ACCURETIC 10-12.5 MG TABLET	54160
ACCURETIC 20-12.5 MG TABLET	54161
ACCURETIC 20-25 MG TABLET	94490
AFIRMELLE-28 TABLET	11534
ALTACE 1.25 MG CAPSULE	48541
ALTACE 10 MG CAPSULE	48544
ALTACE 2.5 MG CAPSULE	48542
ALTACE 5 MG CAPSULE	48543
ALTAVERA-28 TABLET	11530
ALYACEN 1-35 28 TABLET	11474
ALYACEN 7-7-7-28 TABLET	11477
AMABELZ 0.5-1 MG TABLET	98362
AMABELZ 1-0.5 MG TABLET	95046
AMETHIA 0.15-0.03-0.01 MG TABLET	27096
AMETHIA LO TABLET	18167
AMETHYST 90-20 MCG TABLET	98551
AMLODIPINE-BENAZEPRIL 10-20 MG	17604
AMLODIPINE-BENAZEPRIL 10-40 MG	26950
AMLODIPINE-BENAZEPRIL 2.5-10	33093
AMLODIPINE-BENAZEPRIL 5-10 MG	33092
AMLODIPINE-BENAZEPRIL 5-20 MG	33090
AMLODIPINE-BENAZEPRIL 5-40 MG	26949
APRI 28 DAY TABLET	68811
ARANELLE 28 TABLET	11478
ASHLYNA 0.15-0.03-0.01 MG TAB	27096
AUBRA-28 TABLET	11534
AUROVELA 1 MG-20 MCG TABLET	11481
AUROVELA 21 1.5-30 TABLET	11480
AUROVELA 24 FE 1 MG-20 MCG TAB	26629
AUROVELA FE 1.5 MG-30 MCG TAB	68101
AUROVELA FE 1-20 TABLET	68102
AVIANE-28 TABLET	11534
AYUNA-28 TABLET	11530
AZURETTE 28 DAY TABLET	94868
BALCOLTRA TABLET	44336

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
BALZIVA 28 TABLET	11470
BEKYREE 28 DAY TABLET	94868
BENAZEPRIL HCL 10 MG TABLET	48612
BENAZEPRIL HCL 20 MG TABLET	48613
BENAZEPRIL HCL 40 MG TABLET	48614
BENAZEPRIL HCL 5 MG TABLET	48611
BENAZEPRIL-HCTZ 10-12.5 MG TAB	33192
BENAZEPRIL-HCTZ 20-12.5 MG TAB	33193
BENAZEPRIL-HCTZ 20-25 MG TAB	33194
BENAZEPRIL-HCTZ 5-6.25 MG TAB	33191
BEYAZ 28 TABLET	29095
BIJUVA 1-100 MG CAPSULE	45661
BLISOVI 24 FE TABLET	26629
BLISOVI FE 1.5-30 TABLET	68101
BLISOVI FE 1-20 TABLET	68102
BRIELLYN TABLET	11470
CAMRESE 0.15-0.03-0.01 MG TAB	27096
CAMRESE LO TABLET	18167
CAPTOPRIL 100 MG TABLET	01480
CAPTOPRIL 12.5 MG TABLET	01483
CAPTOPRIL 25 MG TABLET	01481
CAPTOPRIL 50 MG TABLET	01482
CAPTOPRIL-HCTZ 25-15 MG TABLET	54940
CAPTOPRIL-HCTZ 25-25 MG TABLET	54941
CAPTOPRIL-HCTZ 50-15 MG TABLET	54942
CAPTOPRIL-HCTZ 50-25 MG TABLET	54943
CAZIAN 28 DAY TABLET	13094
CHARLOTTE 24 FE CHEWABLE TAB	34725
CHATEAL-28 TABLET	11530
CLIMARA 0.025 MG/DAY PATCH	28848
CLIMARA 0.0375 MG/DAY PATCH	20069
CLIMARA 0.05 MG/DAY PATCH	28845
CLIMARA 0.06 MG/DAY PATCH	20068
CLIMARA 0.075 MG/DAY PATCH	28853
CLIMARA 0.1 MG/DAY PATCH	28844
CLIMARA PRO PATCH	20849
COMBIPATCH 0.05-0.14 MG PTCH	69123

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
COMBIPATCH 0.05-0.25 MG PTCH	69124
CRYSSELLE-28 TABLET	11500
CYCLAFEM 1-35-28 TABLET	11474
CYCLAFEM 7-7-7-28 TABLET	11477
DASETTA 1-35-28 TABLET	11474
DASETTA 7/7/7-28 TABLET	11477
DAYSEE 0.15-0.03-0.01 MG TAB	27096
DESOGESTR-ETH ESTRAD ETH ESTRA	94868
DIVIGEL 0.25 MG GEL PACKET	98558
DIVIGEL 0.5 MG GEL PACKET	26659
DIVIGEL 1 MG GEL PACKET	10777
DOTTI 0.025 MG PATCH	28842
DOTTI 0.0375 MG PATCH	28846
DOTTI 0.05 MG PATCH	28840
DOTTI 0.075 MG PATCH	28843
DOTTI 0.1 MG PATCH	28841
DROSP-EE-LEVOMEF 3-0.03-0.451	29382
DROSPIRENONE-EE 3-0.02 MG TAB	26767
DROSPIRENONE-EE 3-0.03 MG TAB	13083
DUAVEE 0.45-20 MG TABLET	35909
ELINEST-28 TABLET	11500
ENALAPRIL MALEATE 10 MG TAB	00961
ENALAPRIL MALEATE 2.5 MG TAB	00963
ENALAPRIL MALEATE 20 MG TAB	00962
ENALAPRIL MALEATE 5 MG TABLET	00960
ENALAPRIL-HCTZ 10-25 MG TABLET	54860
ENALAPRIL-HCTZ 5-12.5 MG TAB	54862
ENPRESSE-28 TABLET	11531
EPANED 1 MG/ML SOLUTION	42337
ESTARYLLA 0.25-0.035 MG TABLET	11300
ESTRACE 0.5 MG TABLET	10772
ESTRACE 1 MG TABLET	10770
ESTRACE 2 MG TABLET	10771
ESTRADIOL 0.025 MG PATCH(1/WK)	28848
ESTRADIOL 0.025 MG PATCH(2/WK)	28842
ESTRADIOL 0.0375MG PATCH(1/WK)	20069
ESTRADIOL 0.0375MG PATCH(2/WK)	28846

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
ESTRADIOL 0.05 MG PATCH (1/WK)	28845
ESTRADIOL 0.05 MG PATCH (2/WK)	28840
ESTRADIOL 0.06 MG PATCH (1/WK)	20068
ESTRADIOL 0.075 MG PATCH(1/WK)	28853
ESTRADIOL 0.075 MG PATCH(2/WK)	28843
ESTRADIOL 0.1 MG PATCH (1/WK)	28844
ESTRADIOL 0.1 MG PATCH (2/WK)	28841
ESTRADIOL 0.5 MG TABLET	10772
ESTRADIOL 1 MG TABLET	10770
ESTRADIOL 2 MG TABLET	10771
ESTRADIOL-NORETH 0.5-0.1 MG TB	98362
ESTRADIOL-NORETH 1-0.5 MG TAB	95046
ESTROSTEP FE-28 TABLET	68105
EVAMIST 1.53 MG/SPRAY	98723
FALMINA-28 TABLET	11534
FAYOSIM TABLET	34465
FEMYNOR 28 TABLET	11300
FOSINOPRIL SODIUM 10 MG TAB	48581
FOSINOPRIL SODIUM 20 MG TAB	48582
FOSINOPRIL SODIUM 40 MG TAB	48580
FOSINOPRIL-HCTZ 10-12.5 MG TAB	15621
FOSINOPRIL-HCTZ 20-12.5 MG TAB	10455
FYAVOLV 0.5 MG -2.5 MCG TABLET	15567
FYAVOLV 1 MG-2.5-MCG TABLET	92296
GENERESS FE CHEWABLE TABLET	29719
GIANVI 3 MG-0.02 MG TABLET	26737
HAILEY 21 1.5 MG-30 MCG TAB	11480
HAILEY 24 FE 1 MG-20 MCG TAB	26629
HAILEY FE 1.5-30 TABLET	68101
HAILEY FE 1-20 TABLET	68102
INTROVALE 0.15-0.03 MG TABLET	20414
ISIBLOOM 28 DAY TABLET	68811
JAIMIESS 0.15-0.03-0.01 MG TAB	27096
JINTELI 1 MG-5 MCG TABLET	92296
JOLESSA 0.15-0.03 MG TABLET	20414
JULEBER 28 DAY TABLET	68811
JUNEL 1 MG-20 MCG TABLET	11481

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
JUNEL 1.5 MG-30 MCG TABLET	11480
JUNEL FE 1 MG-20 MCG TABLET	68102
JUNEL FE 1.5 MG-30 MCG TABLET	68101
JUNEL FE 24 TABLET	26629
KAITLIB FE CHEWABLE TABLET	29719
KARIVA 28 DAY TABLET	94868
KELNOR 1-35 28 TABLET	11490
KELNOR 1-50 TABLET	11491
KURVELO TABLET	11530
LARIN 1.5 MG-30 MCG TABLET	11480
LARIN 21 1-20 TABLET	11481
LARIN 24 FE 1 MG-20 MCG TABLET	26629
LARIN FE 1.5-30 TABLET	68101
LARIN FE 1-20 TABLET	68102
LARISSIA-28 TABLET	11534
LAYOLIS FE CHEWABLE TABLET	29719
LEENA 28 TABLET	11478
LESSINA-28 TABLET	11534
LEVONEST-28 TABLET	11531
LEVONO-E ESTRAD 0.10-0.002-0.01	18167
LEVONOR-ETH ESTRA 0.09-0.02 MG	98551
LEVONOR-ETH ESTRAD 0.15-0.03	11530
LEVONOR-ETH ESTRAD 0.15-0.03	20414
LEVONOR-ETH ESTRAD TRIPHASIC	11531
LEVONORG 0.15MG-EE 20-25-30MCG	34465
LEVORA-28 TABLET	11530
LEVORNOR-ETH ESTRAD 0.1-0.02 MG	11534
LILLOW-28 TABLET	11530
LISINOPRIL 10 MG TABLET	47261
LISINOPRIL 2.5 MG TABLET	47264
LISINOPRIL 20 MG TABLET	47262
LISINOPRIL 30 MG TABLET	47265
LISINOPRIL 40 MG TABLET	47263
LISINOPRIL 5 MG TABLET	47260
LISINOPRIL-HCTZ 10-12.5 MG TAB	88002
LISINOPRIL-HCTZ 20-12.5 MG TAB	88000
LISINOPRIL-HCTZ 20-25 MG TAB	88001

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
LO LOESTRIN FE 1-10 TABLET	29264
LOESTRIN 21 1.5-30 TABLET	11480
LOESTRIN 21 1-20 TABLET	11481
LOESTRIN FE 1.5-30 TABLET	68101
LOESTRIN FE 1-20 TABLET	68102
LOJAIMIESS 0.1-0.02-0.01 TAB	18167
LORYNA 3 MG-0.02 MG TABLET	26737
LOSEASONIQUE TABLET	18167
LOTREL 10-20 MG CAPSULE	17604
LOTREL 10-40 MG CAPSULE	26950
LOTREL 5-10 MG CAPSULE	33092
LOTREL 5-20 MG CAPSULE	33090
LOW-OGESTREL-28 TABLET	11500
LO-ZUMANDIMINE 3 MG-0.02 MG TB	26737
LUTERA-28 TABLET	11534
MARLISSA-28 TABLET	11530
MELODETTA 24 FE CHEWABLE TAB	34725
MENEST 0.3 MG TABLET	11050
MENEST 0.625 MG TABLET	11051
MENEST 1.25 MG TABLET	11052
MENOSTAR 14 MCG/DAY PATCH	22759
MIBELAS 24 FE CHEWABLE TABLET	34725
MICROGESTIN 21 1.5-30 TABLET	11480
MICROGESTIN 21 1-20 MG	11481
MICROGESTIN FE 1.5-30 TAB	68101
MICROGESTIN FE 1-20 TABLET	68102
MILI 0.25-0.035 MG TABLET	11300
MIMVEY 1-0.5 MG TABLET	95046
MINASTRIN 24 FE CHEWABLE TABLET	34725
MOEXIPRIL HCL 15 MG TABLET	48562
MOEXIPRIL HCL 7.5 MG TABLET	48561
MONO-LINYAH 28 TABLET	11300
NATAZIA 28 TABLET	23497
NECON 0.5-35-28 TABLET	11471
NORET-ESTR-FE 0.4-0.035-75	97167
NORETH-ESTRAD-FE 1-0.02-75	34725
NORETH-ESTRAD-FE 1-0.02-75	68102

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
NORETHIND-ETH ESTRAD 0.5-2.5	15567
NORETHIND-ETH ESTRAD 1-0.02 MG	11481
NORETHIN-ESTRA-FE 0.8-0.025 MG	29719
NORETHIN-ETH ESTRAD 1-5	92296
NORG-EE 0.18-0.215-0.25/0.025	18126
NORG-EE 0.18-0.215-0.25/0.035	11301
NORG-ETHIN-ESTRA 0.25-0.035 MG	11300
NORTREL 0.5-35-28 TABLET	11471
NORTREL 1-35 TABLET	11474
NORTREL 7-7-7-28 TABLET	11477
OCELLA 3 MG-0.03 MG TABLET	13083
ORIAHNN 300-1-0.5 MG/300 MG CAPS	48158
PERINDOPRIL ERBUMINE 2 MG TAB	13758
PERINDOPRIL ERBUMINE 4 MG TAB	13759
PERINDOPRIL ERBUMINE 8 MG TAB	93207
PHILITH 0.4-0.035 MG TABLET	11470
PIMTREA 28 DAY TABLET	94868
PIRMELLA 1-35-28 TABLET	11474
PIRMELLA 7-7-7-28 TABLET	11477
PORTIA-28 TABLET	11530
PREFEST TABLET	92689
PREMARIN 0.3 MG TABLET	10943
PREMARIN 0.45 MG TABLET	19975
PREMARIN 0.625 MG TABLET	10942
PREMARIN 0.9 MG TABLET	10944
PREMARIN 1.25 MG TABLET	10945
PREMPRO 0.3-1.5 MG TABLET	20769
PREMPRO 0.45-1.5 MG TABLET	19739
PREMPRO 0.625-2.5 MG TABLET	55731
PREMPRO 0.625-5 MG TABLET	55730
PRINIVIL 10 MG TABLET	47261
QBRELIS 1 MG/ML SOLUTION	41984
QUARTETTE TABLET	34465
QUINAPRIL 10 MG TABLET	27570
QUINAPRIL 20 MG TABLET	27571
QUINAPRIL 40 MG TABLET	27573
QUINAPRIL 5 MG TABLET	27572

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
QUINAPRIL-HCTZ 10-12.5 MG TAB	54160
QUINAPRIL-HCTZ 20-12.5 MG TAB	54161
QUINAPRIL-HCTZ 20-25 MG TAB	94490
RAMIPRIL 1.25 MG CAPSULE	48541
RAMIPRIL 10 MG CAPSULE	48544
RAMIPRIL 2.5 MG CAPSULE	48542
RAMIPRIL 5 MG CAPSULE	48543
RECLIPSEN 28 DAY TABLET	68811
RIVELSA TABLET	34465
SAFYRAL TABLET	29382
SEASONIQUE 0.15-0.03-0.01 TAB	27096
SETLAKIN 0.15-0.03 MG TABLET	20414
SIMLIYA 28 DAY TABLET	94868
SIMPESSE 0.15-0.03-0.01 MG TAB	27096
SKYLA 13.5 MG SYSTEM	33984
SLYND 4 MG TABLET	46373
SPRINTEC 28 DAY DABLET	11300
SRONYX 0.10-0.02 MG TABLET	11534
SYEDA 28 TABLET	13083
TARINA FE 1-20 TABLET	68102
TARKA ER 2-180 MG TABLET	32111
TARKA ER 2-240 MG TABLET	32113
TARKA ER 4-240 MG TABLET	32114
TAYTULLA 1 MG-20 MCG CAPSULE	34576
TILIA FE 28 TABLET	68105
TRANDOLAPRIL 1 MG TABLET	32191
TRANDOLAPRIL 2 MG TABLET	32192
TRANDOLAPRIL 4 MG TABLET	32193
TRANDOLAPR-VERAPAM ER 1-240 MG	32112
TRANDOLAPR-VERAPAM ER 2-180 MG	32111
TRANDOLAPR-VERAPAM ER 2-240 MG	32113
TRANDOLAPR-VERAPAM ER 4-240 MG	32114
TRI FEMYNOR 28 TABLET	11301
TRI-LEGEST FE-28 DAY TABLET	68105
TRI-LINYAH TABLET	11301
TRI-LO-ESTARYLLA	18126
TRI-LO-MARZIA TABLET	18126

Step 9 (history of an agent that may exacerbate HAE)	
Required quantity: 30 days supply	
Look back timeframe: 60 days	
Label Name	GCN
TRI-LO-MILI TABLET	18126
TRI-LO-SPRINTEC TABLET	18126
TRI-MILI 28 TABLET	11301
TRI-SPRINTEC TABLET	11301
TRIVORA-28 TABLET	11531
TYDEMY TABLET	29382
VASERETIC 10-25 MG TABLET	54860
VASOTEC 2.5 MG TABLET	00963
VELIVET 28 DAY TABLET	13094
VIENVA-28 TABLET	11534
VIORELE 28 DAY TABLET	94868
VIVELLE-DOT 0.025 MG PATCH	28842
VIVELLE-DOT 0.0375 MG PATCH	28846
VIVELLE-DOT 0.05 MG PATCH	28840
VIVELLE-DOT 0.075 MG PATCH	28843
VIVELLE-DOT 0.1 MG PATCH	28841
VOLNEA 0.15-0.02-0.01 MG TAB	94868
VYFEMLA 28 TABLET	11470
WERA 0.5/0.035 MG 28 TABLET	11471
WYMZYA FE CHEWABLE TABLET	97167
YASMIN 28 TABLET	13083
YAZ 28 TABLET	26737
ZARAH TABLET	13083
ZESTORETIC 20-12.5 MG TABLET	88000
ZESTORETIC 20-25 MG TABLET	88001
ZOVIA 1-35E TABLET	11490
ZUMANDIMINE 3 MG-0.03 MG TAB	13083



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Clinical Criteria References

1. 2014 ICD-9-CM Diagnosis Codes, Volume 1. 2013. Available at <http://www.icd9data.com/>. Accessed on July 31, 2015.
2. 2014 ICD-10-CM Diagnosis Codes, Volume 1. 2013. Available at <http://www.icd9data.com/>. Accessed on July 31, 2015.
3. Cicardi M, Bork K, Caballero T, et al. Hereditary Angioedema International Working Group. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor deficiency: consensus report of an International Working Group. *Allergy* 2012;67:147-57.
4. Cinryze Prescribing Information. Lexington, MA. Takeda Pharmaceuticals. January 2021.
5. Haegarda Prescribing Information. Kankakee, IL. CSL Behring LLC. September 2020.
6. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2019. Available at www.clinicalpharmacology.com. Accessed on May 15, 2019.
7. Drug Facts and Comparisons. eFacts [online]. 2019. Available from Wolters Kluwer Health, Inc. Accessed on May 15, 2019.
8. Berinert Prescribing Information. Kankakee, IL. CSL Behring LLC. April 2019.
9. Firazyr Prescribing Information. Lexington, MA. Takeda Pharmaceuticals America, Inc. August 2020.
10. Kalbitor Prescribing Information. Burlington, MA. Dyax Corp. March 2015.
11. Ruconest Prescribing Information. Bridgewater, NJ. Pharming Healthcare Inc. April 2020.
12. Takhzyro Prescribing Information. Burlington, MA. Dyax Corp. November 2018.
13. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update. *World Allergy Org J* 2018;11:5.
14. Orladeyo Prescribing Information. Durham, NC. BioCryst Pharmaceuticals, Inc. December 2020.

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
04/10/2014	Presented to the DUR Board
04/25/2014	Initial publication and posting to website
07/31/2015	Review of ICD-9 and ICD-10 codes
06/25/2018	Removed ICD-9 codes GCNs for Haegarda added to 'Drugs Requiring PA' GCN for Firazyr removed from 'Drugs Requiring PA' Logic and logic diagram updated Updated references
03/29/2019	Updated to include formulary statement (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 .) on each 'Drug Requiring PA' table
05/01/2019	Addition of Tahkzyro and agents for treatment of acute HAE attacks (Berinert, Firazyr, Kalbitor and Ruconest). Criteria approved by the DUR Board on April 26, 2019
07/15/2019	Annual review by staff Updated references
02/05/2021	Updated age to ≥ 6 years for Haegarda Updated references
04/23/2021	Revised HAE Agents criteria logic for presentation to the DUR Board <ul style="list-style-type: none"> • Added criteria for Orladeyo (new agent) • Added check for P-gp inducers (drug interaction) for Ruconest and Orladeyo • Added check for agents that may exacerbate HAE • Added check for duplicate therapy with HAE prophylactic agents