

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class

Zelboraf (Vemurafenib)

Clinical Criteria Information Included in this Document

Zelboraf (Vemurafenib)

- **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)
- **References:** clinical publications and sources relevant to this clinical criteria

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

Revision Notes

Annual review by staff
Added renewal criteria
Updated references



Zelboraf (Vemurafenib)

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.

Label Name	GCN
ZELBORAF 240MG TABLET	30332



Zelboraf (Vemurafenib)

Clinical Criteria Logic

Initial Request Criteria:

1. Does the client have a diagnosis of **unresectable or metastatic melanoma or Erdheim-Chester disease** in the last 365 days?
 Yes – Go to #2
 No – Deny
2. Has the presence of the BRAF V600E mutation been confirmed? [Manual]
 Yes – Go to #3
 No – Deny
3. Does the client have 1 claim for a **strong CYP3A4 inhibitor/inducer or a CYP1A2 substrate with a narrow therapeutic index** in the last 90 days?
 Yes – Deny
 No – Approve (365 days)

Renewal Request Criteria:

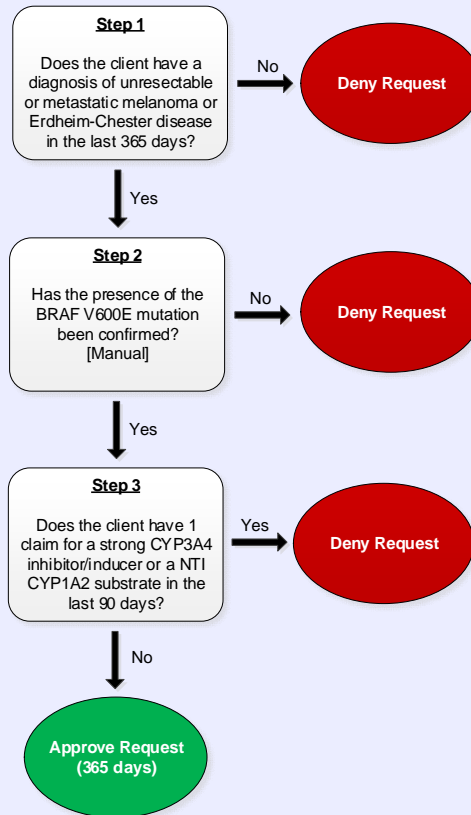
1. Has the client had a claim for Zelboraf in the past 365 days?
 Yes – Go to #2
 No – Go to initial request criteria
2. Does the client have 1 claim for a strong CYP3A4 inhibitor/inducer or a CYP1A2 substrate with a narrow therapeutic index in the last 90 days?
 Yes – Deny
 No – Approve (365 days)



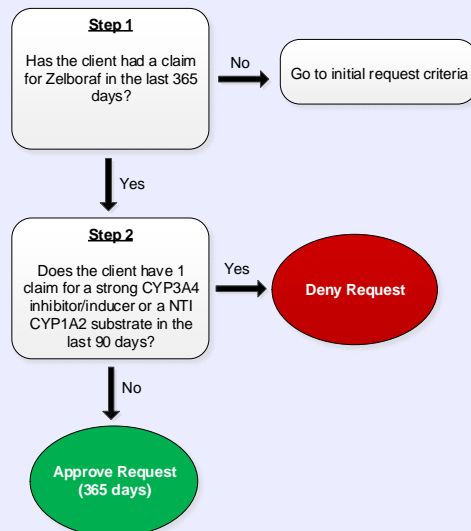
Zelboraf (Vemurafenib)

Clinical Criteria Logic Diagram

Initial Request Criteria:



Renewal Request Criteria:





Zelboraf (Vemurafenib)

Clinical Criteria Supporting Tables

Step 1 (diagnosis of unresectable or metastatic melanoma or Erdheim-Chester disease)

Required quantity: 1

Look back timeframe: 365 days

ICD-10 Code	Description
C439	MALIGNANT MELANOMA OF SKIN, UNSPECIFIED
D039	MELANOMA IN SITU, UNSPECIFIED
E8889	OTHER SPECIFIED METABOLIOOC DISORDERS

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)

Required quantity: 1

Look back timeframe: 90 days

GCN	Label Name
25445	ACTOPLUS MET 15-850MG TABLET
25444	ACTOPLUS MET 15-500MG TABLET
28620	ACTOPLUS MET XR 15-1000MG TABLET
28622	ACTOPLUS MET XR 30-1000MG TABLET
92991	ACTOS 15MG TABLET
93001	ACTOS 30MG TABLET
93011	ACTOS 45MG TABLET
34080	ALOGLIPTIN-PIOGLIT 12.5-15 MG
34083	ALOGLIPTIN-PIOGLIT 12.5-30 MG
34084	ALOGLIPTIN-PIOGLIT 12.5-45 MG
34077	ALOGLIPTIN-PIOGLIT 25-15 MG TB
34078	ALOGLIPTIN-PIOGLIT 25-30 MG TB
34079	ALOGLIPTIN-PIOGLIT 25-45 MG TB
36098	APTIO M 200MG TABLET
36099	APTIO M 400MG TABLET
36106	APTIO M 600MG TABLET
27409	APTIO M 800MG TABLET
27346	ATRIPLA TABLET
92373	BEXAROTENE 75MG CAPSULE
48852	BIAXIN 250 MG TABLET
11671	BIAXIN 250 MG/5 ML SUSPENSION

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
48851	BIAXIN 500 MG TABLET
17460	CARBAMAZEPINE 100 MG TAB CHEW
47500	CARBAMAZEPINE 100 MG/5 ML SUSP
17450	CARBAMAZEPINE 200 MG TABLET
23934	CARBAMAZEPINE ER 100 MG CAP
23932	CARBAMAZEPINE ER 200 MG CAP
27821	CARBAMAZEPINE ER 200 MG TABLET
23933	CARBAMAZEPINE ER 300 MG CAP
27822	CARBAMAZEPINE ER 400 MG TABLET
23934	CARBATROL ER 100 MG CAPSULE
23932	CARBATROL ER 200 MG CAPSULE
23933	CARBATROL ER 300 MG CAPSULE
02363	CARDIZEM 120 MG TABLET
02360	CARDIZEM 30 MG TABLET
02361	CARDIZEM 60 MG TABLET
02326	CARDIZEM CD 120 MG CAPSULE
02323	CARDIZEM CD 180 MG CAPSULE
02324	CARDIZEM CD 240 MG CAPSULE
02325	CARDIZEM CD 300 MG CAPSULE
07460	CARDIZEM CD 360 MG CAPSULE
19180	CARDIZEM LA 120 MG TABLET
19183	CARDIZEM LA 180 MG TABLET
19186	CARDIZEM LA 360 MG TABLET
19187	CARDIZEM LA 420 MG TABLET
02326	CARTIA XT 120MG CAPSULE
02323	CARTIA XT 180MG CAPSULE
02324	CARTIA XT 240MG CAPSULE
02325	CARTIA XT 300MG CAPSULE
11670	CLARITHROMYCIN 125 MG/5 ML SUS
48852	CLARITHROMYCIN 250 MG TABLET
11671	CLARITHROMYCIN 250 MG/5 ML SUS
48851	CLARITHROMYCIN 500 MG TABLET
48850	CLARITHROMYCIN ER 500 MG TAB
25792	COUMADIN 1 MG TABLET
25790	COUMADIN 10 MG TABLET
25791	COUMADIN 2 MG TABLET
25794	COUMADIN 2.5 MG TABLET

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
25796	COUMADIN 3 MG TABLET
25797	COUMADIN 4 MG TABLET
25793	COUMADIN 5 MG TABLET
25798	COUMADIN 6 MG TABLET
25795	COUMADIN 7.5 MG TABLET
26820	CRIXIVAN 200 MG CAPSULE
26822	CRIXIVAN 400 MG CAPSULE
17700	DILANTIN 100 MG CAPSULE
17241	DILANTIN 125 MG/5 ML SUSP
17701	DILANTIN 30 MG CAPSULE
17250	DILANTIN 50 MG INFATAB
02363	DILTIAZEM 120 MG TABLET
02321	DILTIAZEM 12HR ER 120 MG CAP
02322	DILTIAZEM 12HR ER 60 MG CAP
02320	DILTIAZEM 12HR ER 90 MG CAP
02326	DILTIAZEM 24HR ER 120 MG CAP
02323	DILTIAZEM 24HR ER 180 MG CAP
02324	DILTIAZEM 24HR ER 240 MG CAP
02325	DILTIAZEM 24HR ER 300 MG CAP
07460	DILTIAZEM 24HR ER 360 MG CAP
02360	DILTIAZEM 30 MG TABLET
02361	DILTIAZEM 60 MG TABLET
02362	DILTIAZEM 90 MG TABLET
02330	DILTIAZEM ER 120 MG CAPSULE
07463	DILTIAZEM ER 120 MG CAPSULE
02329	DILTIAZEM ER 180 MG CAPSULE
07461	DILTIAZEM ER 180 MG CAPSULE
07462	DILTIAZEM ER 240 MG CAPSULE
02332	DILTIAZEM HCL ER 240 MG CAP
02333	DILTIAZEM HCL ER 300 MG CAP
02328	DILTIAZEM HCL ER 360 MG CAP
94691	DILTIAZEM HCL ER 420 MG CAP
97181	DUETACT 30-2MG TABLET
97180	DUETACT 30-4MG TABLET
00352	ELIXOPHYLLINE 80 MG/ 15 ML ELIX
17450	EPITOL 200 MG TABLET
13781	EQUETRO 100 MG CAPSULE

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
13805	EQUETRO 200 MG CAPSULE
13818	EQUETRO 300 MG CAPSULE
37797	EVOTAZ 300-150MG TABLET
99384	FOSPHENYTOIN 100 MG PE/ 2ML VL
99385	FOSPHENYTOIN 500 MG PE/ 10 ML
40092	GENVOYA TABLET
99318	INTELENCE 100MG TABLET
29424	INTELENCE 200MG TABLET
32035	INTELENCE 25MG TABLET
26760	INVIRASE 200 MG CAPSULE
23952	INVIRASE 500 MG TABLET
49101	ITRACONAZOLE 100 MG CAPSULE
49100	ITRACONAZOLE 10 MG/ML SOLUTION
25792	JANTOVEN 1 MG TABLET
25790	JANTOVEN 10 MG TABLET
25791	JANTOVEN 2 MG TABLET
25794	JANTOVEN 2.5 MG TABLET
25796	JANTOVEN 3 MG TABLET
25797	JANTOVEN 4 MG TABLET
25793	JANTOVEN 5 MG TABLET
25798	JANTOVEN 6 MG TABLET
25795	JANTOVEN 7.5 MG TABLET
99101	KALETRA 100-25 MG TABLET
25919	KALETRA 200-50 MG TABLET
31782	KALETRA 400-100/5 ML ORAL SOLU
25905	KETEK 300 MG TABLET
15175	KETEK 400 MG TABLET
42590	KETOCONAZOLE 200 MG TABLET
64269	LANSOPRAZOL-AMOXICIL-CLARITHRO
37810	LYSODREN 500MG TABLET
19183	MATZIM LA 180MG TABLET
19184	MATZIM LA 240MG TABLET
19185	MATZIM LA 300MG TABLET
19186	MATZIM LA 360MG TABLET
19187	MATZIM LA 420MG TABLET
26101	MODAFINIL 100MG TABLET
26102	MODAFINIL 200MG TABLET

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
29810	MYCOBUTIN 150 MG CAPSULE
17321	MYSOLINE 250MG TABLET
17322	MYSOLINE 50MG TABLET
16406	NEFAZODONE 100MG TABLET
16407	NEFAZODONE 150MG TABLET
16408	NEFAZODONE 200MG TABLET
16409	NEFAZODONE 250MG TABLET
16404	NEFAZODONE 50MG TABLET
31420	NEVIRAPINE 200MG TABLET
31421	NEVIRAPINE 50MG/5ML SUSPENSION
29767	NEVIRAPINE ER 400MG TABLET
26812	NORVIR 100 MG SOFTGEL CAP
28224	NORVIR 100 MG TABLET
26810	NORVIR 80 MG/ML SOLUTION
26502	NOXAFIL 40 MG/ML SUSPENSION
35649	NOXAFIL DR 100 MG TABLET
32137	OMECLAMOX-PAK COMBO PACK
42366	ORKAMBI 100-125MG TABLET
39008	ORKAMBI 200-125MG TABLET
42848	ORKAMBI 150-188 MG GRANULE PKT
36937	ORKAMBI 100-125 MG GRANULE PKT
34080	OSENI 12.5-15MG TABLET
34083	OSENI 12.5-30MG TABLET
34084	OSENI 12.5-45MG TABLET
34077	OSENI 25-15MG TABLET
34078	OSENI 25-30MG TABLET
34079	OSENI 25-45MG TABLET
12975	PHENOBARBITAL 100 MG TABLET
12892	PHENOBARBITAL 130 MG/ML VIAL
12971	PHENOBARBITAL 15 MG TABLET
97706	PHENOBARBITAL 16.2 MG TABLET
12956	PHENOBARBITAL 20 MG/5 ML ELIX
12973	PHENOBARBITAL 30 MG TABLET
97965	PHENOBARBITAL 32.4 MG TABLET
12972	PHENOBARBITAL 60 MG TABLET
97966	PHENOBARBITAL 64.8 MG TABLET
12894	PHENOBARBITAL 65 MG/ML VIAL

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
97967	PHENOBARBITAL 97.2 MG TABLET
15038	PHENYTEK 200 MG CAPSULE
15037	PHENYTEK 300 MG CAPSULE
17241	PHENYTOIN 125 MG/5 ML SUSP
17250	PHENYTOIN 50 MG TABLET CHEW
17200	PHENYTOIN 50 MG/ML VIAL
17700	PHENYTOIN SOD EXT 100 MG CAP
15038	PHENYTOIN SOD EXT 200 MG CAP
15037	PHENYTOIN SOD EXT 300 MG CAP
92991	PIOGLITAZONE HCL 15 MG TABLET
93001	PIOGLITAZONE HCL 30 MG TABLET
93011	PIOGLITAZONE HCL 45 MG TABLET
97181	PIOGLITAZONE-GLIMEPIRIDE 30-2
97180	PIOGLITAZONE-GLIMEPIRIDE 30-4
25444	PIOGLITAZONE-METFORMIN 15-500
25445	PIOGLITAZONE-METFORMIN 15-850
64269	PREVPAC PATIENT PACK
37367	PREZCOBIX 800-150MG TABLET
45911	PRIFTIN 150MG TABLET
17321	PRIMIDONE 250MG TABLET
17322	PRIMIDONE 50MG TABLET
26101	PROVIGIL 100MG TABLET
26102	PROVIGIL 200MG TABLET
29810	RIFABUTIN 150 MG CAPSULE
41260	RIFADIN 150 MG CAPSULE
41261	RIFADIN 300 MG CAPSULE
41470	RIFADIN IV 600 MG VIAL
89800	RIFAMATE CAPSULE
41260	RIFAMPIN 150 MG CAPSULE
41261	RIFAMPIN 300 MG CAPSULE
41470	RIFAMPIN IV 600 MG VIAL
14142	RIFATER TABLET
49100	SPORANOX 10 MG/ML SOLUTION
49101	SPORANOX 100 MG CAPSULE
33130	STRIBILD TABLET
43303	SUSTIVA 200MG CAPSULE
43301	SUSTIVA 50MG CAPSULE

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
15555	SUSTIVA 600MG TABLET
34723	TAFINLAR 50MG CAPSULE
34724	TAFINLAR 75MG CAPSULE
92373	TARGRETIN 75MG CAPSULE
02330	TAZTIA XT 120MG CAPSULE
02329	TAZTIA XT 180MG CAPSULE
02332	TAZTIA XT 240MG CAPSULE
02333	TAZTIA XT 300MG CAPSULE
02328	TAZTIA XT 360MG CAPSULE
37844	TECHNIVIE DOSE PACK
47500	TEGRETOL 100 MG/5 ML SUSP
17450	TEGRETOL 200 MG TABLET
27820	TEGRETOL XR 100 MG TABLET
27821	TEGRETOL XR 200 MG TABLET
27822	TEGRETOL XR 400 MG TABLET
00324	THEO-24 ER 100 MG CAPSULE
00325	THEO-24 ER 200 MG CAPSULE
00326	THEO-24 ER 300 MG CAPSULE
00323	THEO-24 ER 400 MG CAPSULE
01080	THEOPHYLLINE 80 MG/15 ML SOLN
00410	THEOPHYLLINE ER 100 MG TABLET
00411	THEOPHYLLINE ER 200 MG TABLET
00413	THEOPHYLLINE ER 300 MG TAB
00415	THEOPHYLLINE ER 400 MG TABLET
00416	THEOPHYLLINE ER 450 MG TAB
00417	THEOPHYLLINE ER 600 MG TABLET
02330	TIAZAC ER 120MG CAPSULE
02329	TIAZAC ER 180MG CAPSULE
02332	TIAZAC ER 240MG CAPSULE
02333	TIAZAC ER 300MG CAPSULE
02328	TIAZAC ER 360MG CAPSULE
94961	TIAZAC ER 420MG CAPSULE
14979	TRACLEER 125MG TABLET
14978	TRACLEER 62.5MG TABLET
43819	TRACLEER 32 MG TABLET FOR SUSP
36468	TYBOST 150MG TABLET
17498	VFEND 200 MG TABLET

Step 3 (claim for a strong CYP3A4 inhibitor/inducer or CYP1A2 substrate with a narrow therapeutic index)**Required quantity: 1****Look back timeframe: 90 days**

GCN	Label Name
21513	VFEND 40 MG/ML SUSPENSION
17497	VFEND 50 MG TABLET
17498	VFEND 200 MG TABLET
17499	VFEND IV 200 MG VIAL
29941	VICTRELIS 200 MG CAPSULE
37614	VIEKIRA PAK
41932	VIEKIRA XR TABLET
40312	VIRACEPT 250 MG TABLET
19717	VIRACEPT 625 MG TABLET
31420	VIRAMUNE 200MG TABLET
31421	VIRAMUNE 50MG/5ML SUSPENSION
30935	VIRAMUNE XR 100MG TABLET
29767	VIRAMUNE XR 400MG TABLET
17498	VORICONAZOLE 200 MG TABLET
17499	VORICONAZOLE 200 MG VIAL
21513	VORICONAZOLE 40 MG/ML SUSP
17497	VORICONAZOLE 50 MG TABLET
25792	WARFARIN SODIUM 1 MG TABLET
25790	WARFARIN SODIUM 10 MG TABLET
25791	WARFARIN SODIUM 2 MG TABLET
25794	WARFARIN SODIUM 2.5 MG TABLET
25796	WARFARIN SODIUM 3 MG TABLET
25797	WARFARIN SODIUM 4 MG TABLET
25793	WARFARIN SODIUM 5 MG TABLET
25798	WARFARIN SODIUM 6 MG TABLET
25795	WARFARIN SODIUM 7.5 MG TABLET
33183	XTANDI 40MG CAPSULE
36884	ZYDELIG 100MG TABLET
36885	ZYDELIG 150MG TABLET



Zelboraf (Vemurafenib)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2024. Available at <http://www.clinicalpharmacology.com>. Accessed on July 31, 2024.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on July 31, 2024.
3. Cicardi M, Bork K, Caballero T, et al. on behalf of 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. 2015 ICD-10-CM Diagnosis Codes. 2015. Available at www.icd10data.com. Accessed on April 3, 2015.
5. Zelboraf Prescribing Information. South San Francisco, CA. Genentech. May 2020.
6. Sosman JA. Overview of the management of advanced cutaneous melanoma. In: UpToDate, Atkins MB (Ed), UpToDate, Waltham, MA, 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
01/30/2014	Presented to the DUR Board
03/03/2014	Initial publication and posting to website
04/03/2015	Updated to include ICD-10s
04/12/2018	Annual review by staff Removed ICD-9 codes Added diagnosis of Erdheim-Chester disease to question #2 in logic and logic diagram Added question #4 to logic and logic diagram Updated Table 2 Added Table 4 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
04/30/2021	Annual review by staff Added diagnosis of Erdheim-Chester disease Added GCNs for alogliptin/pioglitazone (34080, 34083, 34084, 34077, 34078, 34079); fosphenytoin (99384, 99385); itraconazole (49100); Orkambi (42848, 36937); Tracleer (43819); Vfend (17498) to Table 4 Updated references
10/08/2021	Removed specialist requirement from criteria
10/17/2023	Corrected numbering on criteria logic
12/08/2023	Annual review by staff Updated references
07/31/2024	Annual review by staff Added renewal criteria Updated references