Fentanyl Agents
Clinical Edit Criteria

Drug/Drug Class:

Fentanyl Agents

Superior HealthPlan follows the guidance of the Texas Vendor Drug Program (VDP) for all clinical edit criteria. Superior has adjusted the clinical criteria to ease the prior authorization process regarding this clinical edit. Changes to the original edit are noted in yellow highlight within this document. Fentora criteria has been shortened as steps 4-13 from the original criteria have been removed.

The original clinical edit can be referenced at the VDP website located at https://paxpress.txpa.hidinc.com/fentanyl.pdf.

Clinical Edit Information Included in this Document:

Abstral (Fentanyl Sublingual Tablet) / Lazanda (Fentanyl Nasal Spray) / Subsys (Fentanyl Sublingual Spray
Actiq (Oral Transmucosal Fentanyl)
Duragesic (Transdermal Fentanyl)
Fentora (Buccal Fentanyl)

- 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 edit criteria logic.
- Diagnosis codes or drugs in step logic: a list of diagnosis codes or drug information and additional step logic, claims and lookback period information.
- Supporting tables: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable. The supporting tables by VDP are so large that a cross reference has been provided to the original VDP edit as Superior implements the VDP's logic inside these tables.
- Clinical edit references: clinical edit references as provided by the Texas Vendor Drug Program.
- Publication history: to track when the eased criteria was put into production and any updates since this time.

Please note: All tables are provided by original VDP Edit.

Drugs Requiring Prior Authorization Abstral / Lazanda / Subsys:

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.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
ABSTRAL 100MCG SUBLINGUAL TABLETS	16178
ABSTRAL 200MCG SUBLINGUAL TABLETS	16179
ABSTRAL 300MCG SUBLINGUAL TABLETS	16181
ABSTRAL 400MCG SUBLINGUAL TABLETS	16182
ABSTRAL 600MCG SUBLINGUAL TABLETS	16183
ABSTRAL 800MCG SUBLINGUAL TABLETS	16184
LAZANDA 100MCG NASAL SPRAY	27648
LAZANDA 300MCG NASAL SPRAY	41539
LAZANDA 400MCG NASAL SPRAY	29146
SUBSYS 1,200MCG SPRAY	31596
SUBSYS 1,600MCG SPRAY	31597
SUBSYS 100MCG SPRAY	31187
SUBSYS 200MCG SPRAY	31189
SUBSYS 400MCG SPRAY	31188
SUBSYS 600MCG SPRAY	31192
SUBSYS 800MCG SPRAY	31193

Superior HealthPlan Clinical Criteria Logic Abstral / Lazanda / Subsys:

1. Is the client ≥ 18 years of age?
    [ ] Yes (Go to #2)
    [ ] No (Deny)

2. Does the client have a diagnosis of malignancy in the last 730 days?
    [ ] Yes (Go to #4)
    [ ] No (Go to #3)

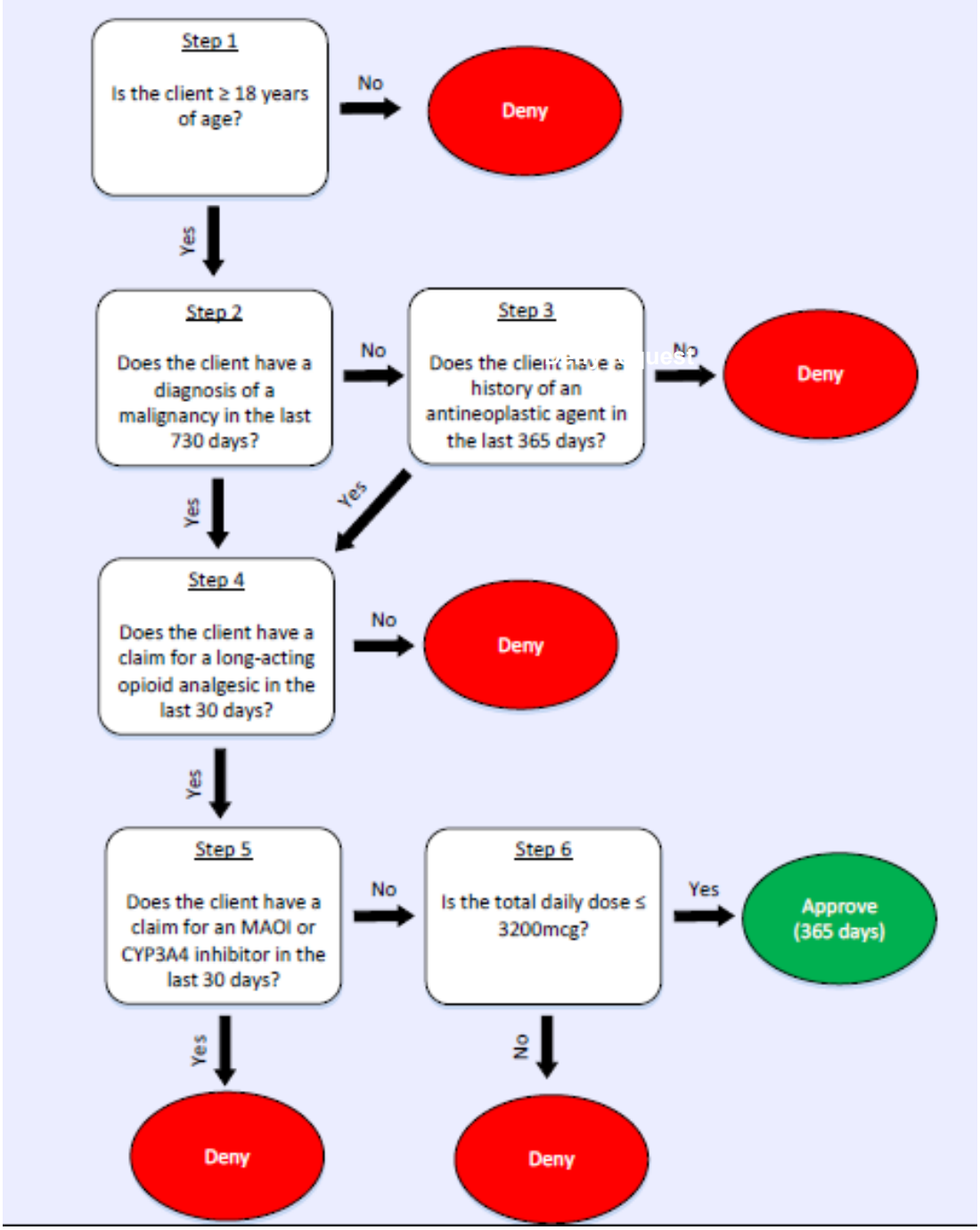
3. Does the client have a history of antineoplastic therapy in the last 365 days?
    [ ] Yes (Go to #4)
    [ ] No (Deny)

4. Does the client have a claim for a long-acting opioid analgesic in the last 30 days?
    [ ] Yes (Go to #5)
    [ ] No (Deny)

5. Does the patient have a claim for an MAOI or CYP3A4 inhibitor in the last 30 days?
    [ ] Yes (Deny)
    [ ] No (Go to #6)

6. Is the total daily dose less than or equal to (≤) 3200mcg?
    [ ] Yes (Approve – 365)
    [ ] No (Deny)

Superior HealthPlan Clinical Edit Logic Diagram Abstral / Lazanda / Subsys:



Drugs Requiring Prior Authorization Actiq (Transmucosal Fentanyl):

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Drugs Requiring Prior Authorization	
Label Name	**GCN**
ACTIQ 1,200 MCG LOZENGE	19193
ACTIQ 1,600 MCG LOZENGE	19194
ACTIQ 200 MCG LOZENGE	19204
ACTIQ 400 MCG LOZENGE	19206
ACTIQ 600 MCG LOZENGE	19191
ACTIQ 800 MCG LOZENGE	19192
FENTANYL CIT OTFC 1,200 MCG	19193
FENTANYL CIT OTFC 1,600 MCG	19194
FENTANYL CITRATE OTFC 200 MCG	19204
FENTANYL CITRATE OTFC 400 MCG	19206
FENTANYL CITRATE OTFC 600 MCG	19191
FENTANYL CITRATE OTFC 800 MCG	19192

Superior HealthPlan Clinical Criteria Logic Actiq (Transmucosal Fentanyl)

1. Is the client less than (<) 16 years of age?
    [ ] Yes (Deny)
    [ ] No (Go to #2)

2. Does the client have a diagnosis of cancer or fibrotic lung disease in the last 730 days?
    [ ] Yes (Go to #5)
    [ ] No (Go to #3)

3. Does the client have a history of antineoplastic therapy in the last 365 days?
    [ ] Yes (Go to #5)
    [ ] No (Go to #4)

4. Does the client have a diagnosis of CNMP in the last 365 days?
    [ ] Yes (Go to #5)
    [ ] No (Deny)

5. Does the client have less than or equal to (≤) 7 days of opioid therapy in the last 30 days?
    [ ] Yes (Deny)
    [ ] No (Go to #6)

6. Does the client have a claim for an MAOI or a strong/moderate CYP3A4 inhibitor in the last 30 days?
    [ ] Yes (Deny)
    [ ] No (Go to #7)

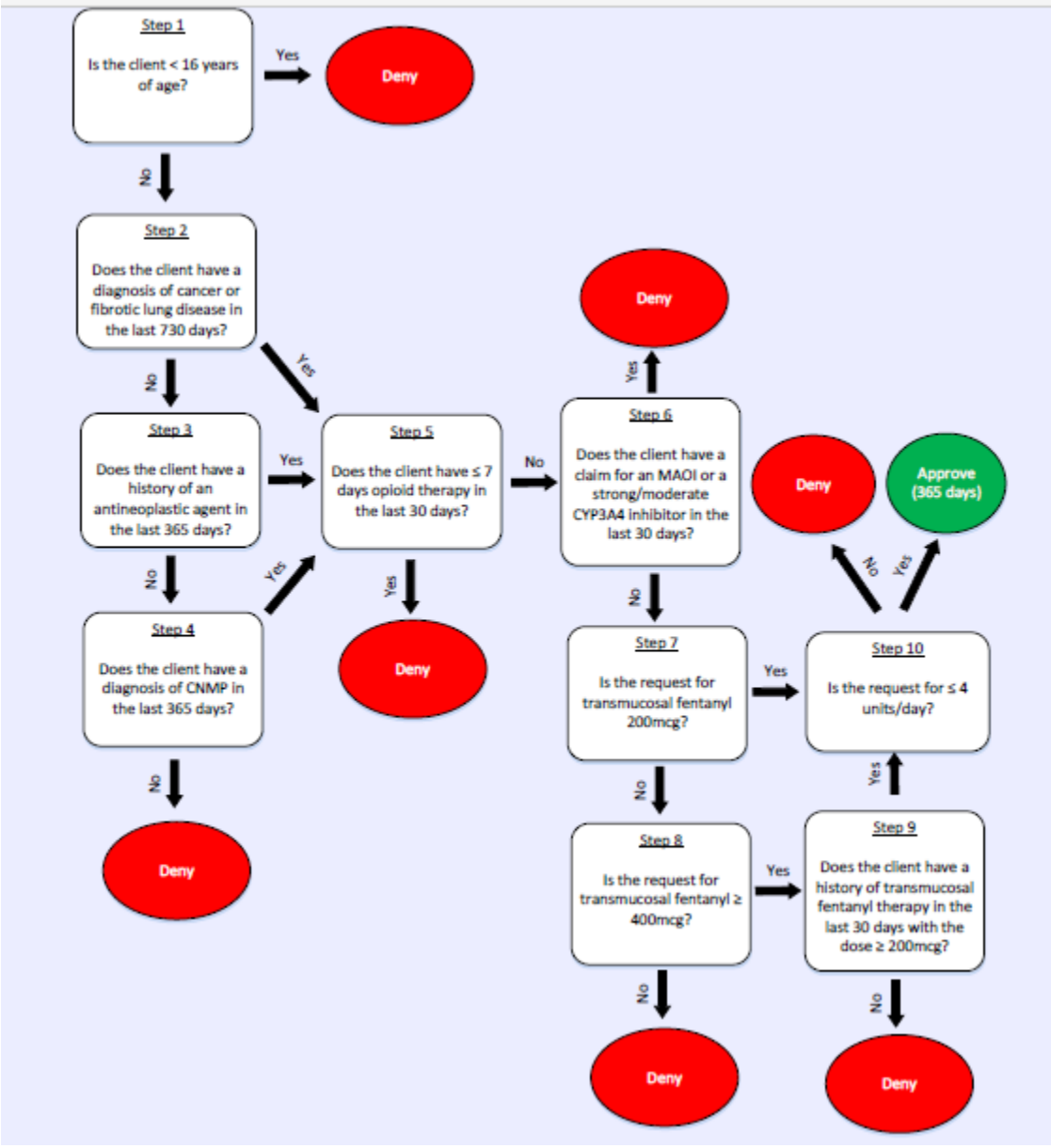
7. Is the request for transmucosal fentanyl 200mcg?
    [ ] Yes (Go to #10)
    [ ] No (Go to #8)

8. Is the request for transmucosal fentanyl greater than or equal to (≥) 400mcg?
    [ ] Yes (Go to #9)
    [ ] No (Deny)

9. Does the client have a history of transmucosal fentanyl therapy in the last 30 days with the dose greater than or equal to (≥) 200mcg?
    [ ] Yes (Go to #10)
    [ ] No (Deny)

10. Is the request for less than or equal to (≤) 4 units per day?
    [ ] Yes (Approve – 365 days)
    [ ] No (Deny)

Superior HealthPlan Clinical Edit Logic Diagram Actiq (Transmucosal Fentanyl):



Drugs Requiring Prior Authorization Duragesic (Transdermal Fentanyl):

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.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
DURAGESIC 100 MCG/HR PATCH	19203
DURAGESIC 12 MCG/HR PATCH	24635
DURAGESIC 25 MCG/HR PATCH	19200
DURAGESIC 50 MCG/HR PATCH	19201
DURAGESIC 75 MCG/HR PATCH	19202
FENTANYL 100 MCG/HR PATCH	19203
FENTANYL 12 MCG/HR PATCH	24635
FENTANYL 25 MCG/HR PATCH	19200
FENTANYL 37.5 MCG/HR PATCH	37952
FENTANYL 50 MCG/HR PATCH	19201
FENTANYL 62.5 MCG/HR PATCH	37947
FENTANYL 75 MCG/HR PATCH	19202
FENTANYL 87.5 MCG/HR PATCH	37948

Superior HealthPlan Clinical Criteria Logic Duragesic (Transdermal Fentanyl):

1. Does the client have a diagnosis of cancer or fibrotic lung disease in the last 730 days?
    [ ] Yes (Go to #6)
    [ ] No (Go to #2)

2. Does the client have a history of an antineoplastic agent in the last 365 days?
    [ ] Yes (Go to #6)
    [ ] No (Go to #3)

3. Does the client have less than or equal to (≤) 7 days of opioid therapy in the last 30 days?
    [ ] Yes (Go to #4)
    [ ] No (Go to #6)

4. Does the client have a diagnosis of chronic non-malignant pain in the last 365 days?
    [ ] Yes (Go to #6)
    [ ] No (Go to #5)

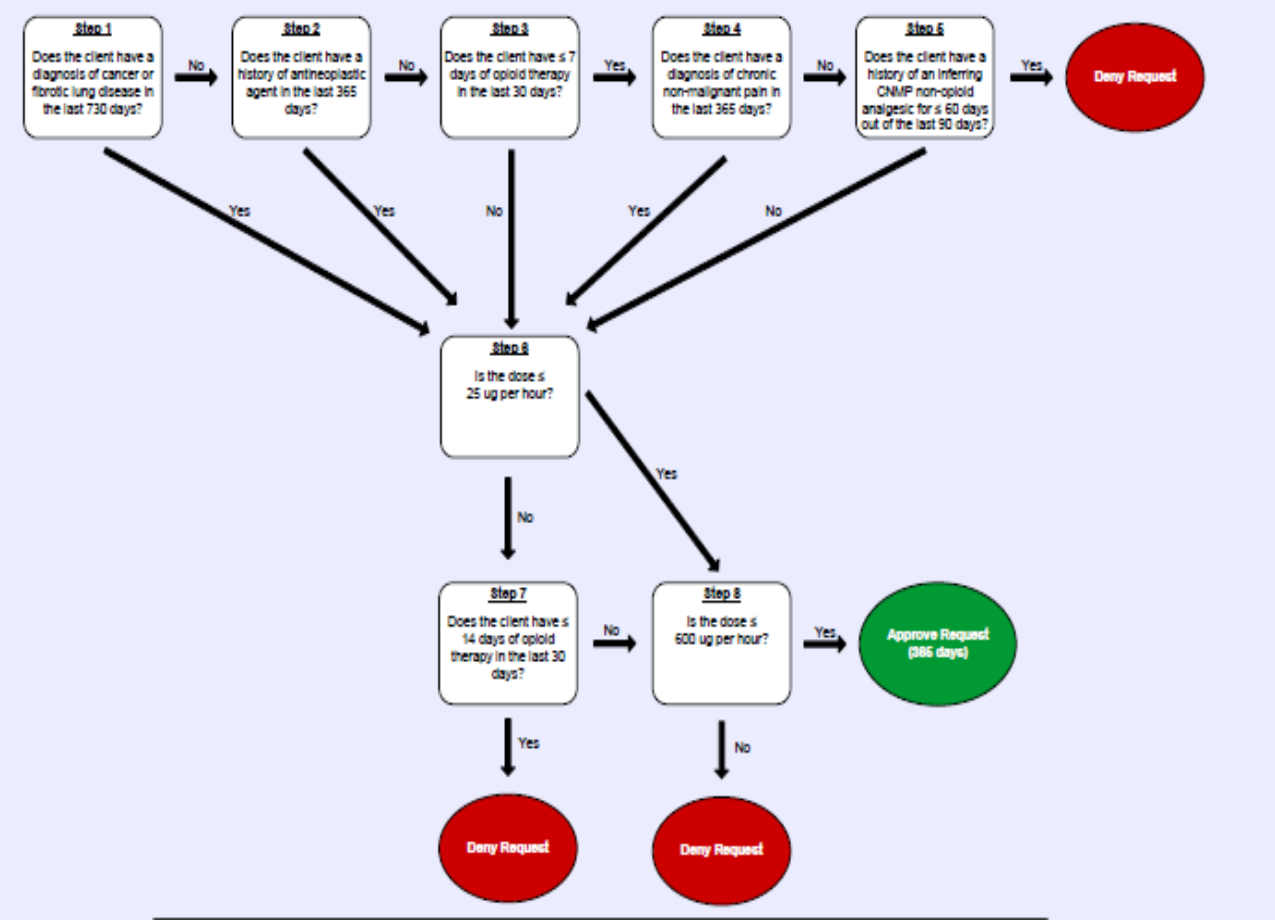
5. Does the client have a history of an inferring CNMP non-opioid analgesic for less than or equal to (≤) 60 days out of the last 90 days?
    [ ] Yes (Deny)
    [ ] No (Go to #6)

6. Is the dose less than or equal to (≤) 25ug per hour?
    [ ] Yes (Go to #8)
    [ ] No (Go to #7)

7. Does the client have less than or equal to (≤) 14 days of opioid therapy in the last 30 days?
    [ ] Yes (Deny)
    [ ] No (Go to #8)

8. Is the dose less than or equal to (≤) 600ug per hour?
    [ ] Yes (Approve – 365 days)
    [ ] No (Deny)

Superior HealthPlan Clinical Edit Logic Duragesic (Transdermal Fentanyl):



Drugs Requiring Prior Authorization Fentora (Buccal Fentanyl):

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.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
FENTORA 100 MCG BUCCAL TABLET	97280
FENTORA 200 MCG BUCCAL TABLET	97281
FENTORA 400 MCG BUCCAL TABLET	97283
FENTORA 600 MCG BUCCAL TABLET	97284
FENTORA 800 MCG BUCCAL TABLET	97285

Superior HealthPlan Clinical Criteria Logic Fentora (Buccal Fentanyl):

1. Is the client greater than or equal to (≥) 18 years of age?
    [ ] Yes (Go to #2)
    [ ] No (Deny)

2. Does the client have a diagnosis of malignant cancer in the last 730 days?
    [ ] Yes (Approve – 365 days)
    [ ] No (Go to #3)

3. Does the client have a history of an antineoplastic agent in the last 365 days?
    [ ] Yes (Approve – 365 days)
    [ ] No (Deny)

~~4. Does the client have a claim for an MAOI or CYP3A4 inhibitor in the last 30 days?~~
    ~~[ ] Yes (Deny)~~
    ~~[ ] No (Go to #5)~~

~~5. Does the client have at least 12 days supply of opioid therapy in the last 14 days?~~
    ~~[ ] Yes (Go to #6)~~
    ~~[ ] No (Deny)~~

~~6. Does the client have a history of buccal fentanyl in the last 35 days?~~
    ~~[ ] Yes (Go to #13)~~
    ~~[ ] No (Go to #7)~~

~~7. Does the client have a history of opioid tolerance with defined oral morphine, transdermal fentanyl, oxycodone, hydromorphone, OR oxymorphone therapy in the last 30 days?~~
    ~~[ ] Yes (Go to #8)~~
    ~~[ ] No (Deny)~~

~~8. Is the request for buccal fentanyl 100mcg?~~
    ~~[ ] Yes (Go to #13)~~
    ~~[ ] No (Go to #9)~~

~~9. Is the request for buccal fentanyl 200mcg?~~
    ~~[ ] Yes (Go to #10)~~
    ~~[ ] No (Go to #11)~~

~~10. Does the client have a claim for Actiq 600, 800, 1200 or 1600mcg in the last 35 days?~~
    ~~[ ] Yes (Go to #13)~~

[ ] No (Deny)

11. Is the request for buccal fentanyl 400mcg?

[ ] Yes (Go to #12)

[ ] No (Deny)

12. Does the client have a history of Actiq 1200 or 1600mcg in the last 35 days?

[ ] Yes (Go to #13)

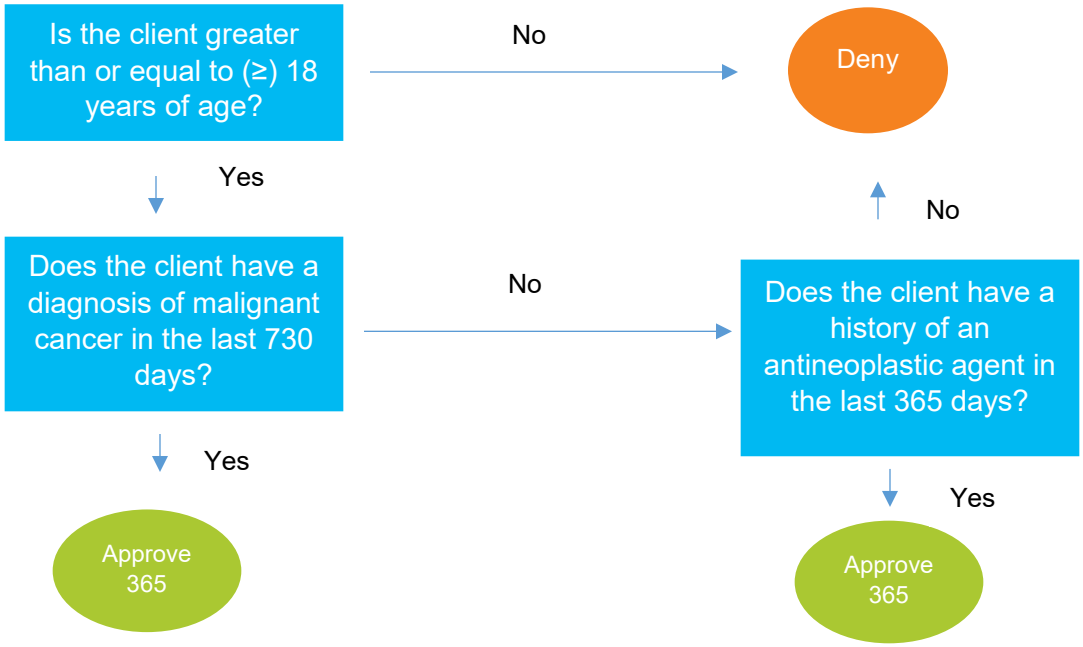
[ ] No (Deny)

13. Is the request for less than or equal to (≤) 4 units/day?

[ ] Yes (Approve – 365 days)

[ ] No (Deny)

Superior HealthPlan Clinical Edit Logic Fentora (Buccal Fentanyl):



Clinical Criteria Supporting Tables Fentanyl Agents:

Due to the size of the supporting tables provided by Texas Vendor Drug Program please reference https://paxpress.txpa.hidinc.com/fentanyl.pdf for all supporting table documentation.

Clinical Criteria References:

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2016. Available at www.clinicalpharmacology.com. Accessed on August 30, 2016.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on August 30, 2016.
3. 2015 ICD-9-CM Diagnosis Codes. 2015. Available at **www.icd9data.com**. Accessed on April 3, 2015.
4. 2015 ICD-10-CM Diagnosis Codes. 2015. Available at **www.icd10data.com**. Accessed on April 3, 2015.
5. American Medical Association data files. 2015 ICD-9-CM Diagnosis Codes. Available at **www.commerce.ama-assn.org**.
6. American Medical Association data files. 2015 ICD-10-CM Diagnosis Codes. Available at **www.commerce.ama-assn.org**.
7. Abstral Prescribing Information. Sentynl Therapeutics, Inc. Solana Beach, CA. November 2014.
8. Lazanda Prescribing Information. Newark, CA. Depomed, Inc. March 2015.
9. Subsys Prescribing Information. Chandler, AZ. Insys Therapeutics, Inc. December 2014.
10. Actiq Prescribing Information. Frazer, PA. Cephalon, Inc. December 2011.
11. Duragesic Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals, Inc. April 2014.
12. Fentora Prescribing Information. North Wales, PA. Teva Pharmaceuticals USA. February 2013.
13. Xtampza Prescribing Information. Cincinnati, OH. Collegium Pharmaceutical, Inc. April 2016.

Publication History:

Publication	Notes
11/5/18	Criteria created and cross referenced to VDP criteria.
2/7/19	Added Fentora criteria and cross referenced to VDP criteria
5/15/20	Updated VDP website link 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