SmartPA Criteria Proposal

Drug/Drug Class:	Tramadol-Like Agents PDL Edit
First Implementation Date:	July 23, 2003
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state specific preferred drug list.

Why Issue Selected: Tramadol is a fully synthetic opioid pain medication used to treat moderate to moderately severe pain. When taken as an immediate-release oral formulation, the onset of pain relief is usually within an hour. Tramadol binds to the Mu-opioid receptor and inhibits the reuptake of serotonin and norepinephrine. Serious side effects may include seizures, increased risk of suicide, serotonin syndrome, decreased alertness and drug addiction. Common side effects include constipation, itchiness, and nausea. In fall 2014, the DEA reclassified the painkiller tramadol as a Schedule IV controlled substance because it can be addictive, misused, and diverted.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Tramadol 50 mg (gen Ultram®) • Tramadol ER Tabs (gen Ultram® ER) • Tramadol/APAP	• ConZip® • Nucynta® • Nucynta® ER • Qdolo® • Tramadol 100 mg • Tramadol ER Caps (gen ConZip®) • Tramadol ER Tabs (gen Ryzolt™) • Ultracet® • Ultram®

Type of Criteria:
☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Tramadol-Like Agents
- Age range: all appropriate MO Healthnet Participants aged 12 years or older

Approval Criteria

- Failure to achieve desired therapeutic outcomes with a trial on 2 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For tramadol and tramadol/APAP: participants aged 12 years or older
- For tramadol ER:
  - Participants aged 12 years or older **AND**
  - History of previous stabilization on an immediate-release tramadol product (defined as 60/90 days)
- For tapentadol and tapentadol ER: participants aged 18 years or older
- **For Qdolo: Clinical Consultant Review required**
- Participant must also meet all approval criteria contained within the Morphine Milligram Equivalent Accumulation Clinical Edit

Denial Criteria

- Lack of adequate trial on required preferred agents
- Documented history of seizures
- Documented history of opioid abuse treatment in the last 45 days
- Claim history of monoamine-oxidase inhibitor in the last 45 days
- For tramadol ER, tapentadol and tapentadol ER: history of opioid use disorder – therapy will be subject to Clinical Consultant review
- Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for an opioid (excluding buprenorphine tablets and buprenorphine/naloxone combinations) AND
  - Participant has history of > 3 days of select oral benzodiazepine therapy (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam) in the past 60 days AND
  - Participant lacks history of at least 1 claim for an opioid emergency reversal agent in the past 2 years
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Units Per Day
CONZIP 100 MG CAPSULE	TRAMADOL HYDROCHLORIDE	3
CONZIP 200 MG CAPSULE	TRAMADOL HYDROCHLORIDE	1
CONZIP 300 MG CAPSULE	TRAMADOL HYDROCHLORIDE	1
NUCYNTA 100 MG TABLET	TAPENTADOL HYDROCHLORIDE	7
NUCYNTA 50 MG TABLET	TAPENTADOL HYDROCHLORIDE	14
NUCYNTA 75 MG TABLET	TAPENTADOL HYDROCHLORIDE	9
NUCYNTA ER 100 MG TABLET	TAPENTADOL HYDROCHLORIDE	5
NUCYNTA ER 150 MG TABLET	TAPENTADOL HYDROCHLORIDE	3
NUCYNTA ER 200 MG TABLET	TAPENTADOL HYDROCHLORIDE	2
NUCYNTA ER 250 MG TABLET	TAPENTADOL HYDROCHLORIDE	2
NUCYNTA ER 50 MG TABLET	TAPENTADOL HYDROCHLORIDE	10
QDOLO 5 MG/ML SOLUTION	**TRAMADOL HYDROCHLORIDE**	**60 mL**
RYZOLT ER 100 MG TABLET	TRAMADOL HYDROCHLORIDE	3
RYZOLT ER 200 MG TABLET	TRAMADOL HYDROCHLORIDE	1
RYZOLT ER 300 MG TABLET	TRAMADOL HYDROCHLORIDE	1

TRAMADOL HCL ER 150 MG CAPSULE	TRAMADOL HYDROCHLORIDE	2
ULTRACET TABLET	TRAMADOL/ACETAMINOPHEN	8
ULTRAM 50 MG TABLET	TRAMADOL HYDROCHLORIDE	8 (ages 12-75) 6 (ages >75)
ULTRAM ER 100 MG TABLET	TRAMADOL HYDROCHLORIDE	3
ULTRAM ER 200 MG TABLET	TRAMADOL HYDROCHLORIDE	1
ULTRAM ER 300 MG TABLET	TRAMADOL HYDROCHLORIDE	1

Required Documentation

Laboratory Results: ☐ Progress Notes: ☐
MedWatch Form: ☐ Other: ☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: "Tramadol-Like Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: "Tramadol-Like Agents", UMKC-DIC; October 2021.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.