Louisiana Medicaid
Age Limit Override Criteria for Tramadol and Tramadol Combination Products

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tramadol and tramadol combination products for *recipients 12 years of age to less than 18 years of age*.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**, and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is at least 12 years of age but less than 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of pain severe enough to require an opioid analgesic; **AND**
- There has been a treatment failure, intolerable side effect with, or contraindication to a preferred analgesic [name of analgesic and dates of use must be **stated on the request**]; **AND**
- The prescriber **states on the request** that the requested medication is **NOT** being used for postoperative management following tonsillectomy and/or adenoidectomy; **AND**
- The prescriber **states on the request** that the recipient **DOES NOT** have other risk factors that may increase their sensitivity to the respiratory depressant effects of tramadol. Risk factors include conditions associated with hypoventilation such as
    - postoperative status; **OR**
    - obstructive sleep apnea; **OR**
    - obesity; **OR**
    - severe pulmonary disease; **OR**
    - neuromuscular disease; **OR**
    - concomitant use of other medications that cause respiratory depression; **OR**
- The prescriber **states on the request** that the benefits outweigh the risks in recipients who have risk factors that may increase their sensitivity to the respiratory depressant effects of tramadol products; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 3 months or up to the recipients 18th birthday, whichever is less.

References

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Qdolo (tramadol) [package insert]. Athens, GA: Athena Bioscience; September 2020. https://qdolo.com/wp-content/uploads/2020/10/QDOLO-Prescribing-Information.pdf

Seglentis (celecoxib/tramadol) [package insert]. Montgomery, AL: Kowa Pharmaceuticals America; October 2021. https://www.kowapharma.com/documents/SEGLENTIS_Prescribing_Information.pdf

Ultracet (tramadol/acetaminophen) [package insert]. Titusville, NJ: Janssen Pharmaceuticals; September 2021. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ULTRACET-pi.pdf

Ultram (tramadol) [package insert]. Titusville, NJ: Janssen Pharmaceuticals; September 2021. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ULTRAM-pi.pdf

Ultram ER (tramadol ER) [package insert]. Titusville, NJ: Janssen Pharmaceuticals; August 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021692s015lbl.pdf

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