| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
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| Original Development Date:<br>Original Effective Date:<br>Revision Date: | August 23, 2012<br><br>April 22, 2022 |

# BUTALBITAL-CONTAINING PRODUCTS

APPROVAL AMOUNT: UP TO A MAXIMUM OF ANOTHER 120 TABLETS/CAPSULES OR 180 ML (for the liquid) ABOVE THE EXISTING QUANTITY LIMITATION (SEE SUMMARY OF DRUG LIMITATIONS).

REVIEW CRITERIA:

- ***Tensions (Muscle Contraction) Headaches****: (for requests exceeding the quantity limit)*
  - Must have a chronic history of attacks (per progress notes).
  - Must be prescribed or recommended upon consultation with a specialist (eg. neurologist) as per progress notes submitted.
  - Must have had trial and failure of at least three of the four therapies in the past 365 days:
    - NSAIDs (eg. ibuprofen, naproxen)
    - Tricyclics (eg. amitriptyline)
    - Muscle relaxants (eg. tizanidine)
    - Non-drug Therapies (relaxation training, cognitive behavior therapy, EMG biofeedback)

- ***Migraine Headaches****:(for requests exceeding the quantity limit)*
  - Must have a chronic history of attacks (per progress notes).
  - Must have current (within past 30 days) treatment failure of prophylaxis therapy (eg. metoprolol, topiramate, amitriptyline).
  - Must be prescribed or recommended upon consultation with a specialist (eg. neurologist) as per progress notes submitted.
  - Must have had trial and failure of at least one medication from each the classes of therapy below in the past 365 days:
    - NSAIDs (eg. ibuprofen, naproxen)
    - Triptans [eg. Axert *(almotriptan)*,Maxalt (*riztriptan*), Imitrex *(sumatriptan)*, Relpax *(eletriptan)*, Treximet *(sumatriptan/naproxen)*, Amerge (*nararitpan)*, Frova (*frovatriptan*, Zomig *(zolmitriptan)*]

DOSING & ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/.