Gralise® / Horizant® (gabapentin ER tablets)

FDA INDICATIONS AND USAGE[1,2]

- Gralise® is indicated for the treatment of Postherpetic Neuralgia.
  - Supplied in 300mg and 600mg tablets
- Horizant® is indicated for the treatment of Postherpetic Neuralgia and primary Restless Leg Syndrome in adults.
  - Supplied in 300mg and 600mg tablets

APPROVAL CRITERIA[1,2,3]

1. Patient has the diagnosis of Postherpetic Neuralgia; **AND**
2. Patient has had an adequate trial (8 weeks) of generic gabapentin at a dose of at least 1,800mg per day; **OR**
3. There is documentation that the patient has been using one of these agents and the prescriber states that the patient is responding to therapy; **OR**
4. Patient has contraindication to generic gabapentin ingredients and had a clinically adverse event as a result of use.

OR

1. Patient has the diagnosis of Restless Leg Syndrome; **AND**
2. The request is for Horizant®; **AND**
3. The dose does not exceed 600mg; **AND**
4. Patient has had an adequate trial of pramipexole (4 weeks) and ropinirole (4 weeks); **OR**
5. There is documentation that the patient has been using Horizant® and the prescriber states that the patient is responding to therapy; **OR**
6. Patient has contraindication to pramipexole or ropinirole ingredients and had a clinically adverse event as a result of use.

DENIAL CRITERIA

1. Patient does not have the diagnosis of Postherpetic Neuralgia; **AND**
2. Patient has not had an adequate trial (8 weeks) of generic gabapentin at a dose of at least 1,800mg per day; **OR**
3. There is no documentation that the patient has been using one of these agents and the prescriber has not stated that the patient is responding to therapy.

OR

1. Patient does not have the diagnosis of Restless Leg Syndrome; **AND**
2. The request is not for Horizant®; **AND**
3. The dose exceeds 600mg; **AND**
4. Patient has not had an adequate trial of pramipexole (4 weeks) and ropinirole (4 weeks); **OR**
5. There is no documentation that the patient has been using Horizant® and the prescriber has not stated that the patient is responding to therapy.

CAUTIONS[1,2]

- Gralise® and Horizant® are not interchangeable with other gabapentin products.
- Gralise® and Horizant® may increase suicidal thoughts or behaviors.
- Dose adjustments may be needed for patients with renal impairment.

DURATION OF APPROVAL

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 12 months with reported improvement

QUANTITY LIMIT

- Gralise® maximum daily dose not to exceed 1,800mg per day
  - 30 - 300mg tablets per month
  - 90 - 600mg tablets per month
- Horizant® maximum daily dose not to exceed 1,200mg per day
  - 30 - 300mg tablets per month
  - 60 - 600mg tablets per month

REFERENCES / FOOTNOTES:

1. Gralise® [package insert]. Newark, CA: Depomed, Inc.; December 2012. Available at: https://www.gralise.com. Accessed September 4, 2018.
2. Horizant® [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.; October 2016. Available at: https://horizant.com. Accessed September 4, 2018.
3. Winkelman WJ, Armstrong MJ, Chadhuri KR, Ondo W, Trenkwalder C, Zee PC,Gronseth GS, Gloss D, Zesiewicz T. Practice guideline summary: Treatment of restless legs syndrome in adults. Neurology. December 13, 2016; 87 (24).