Definition

Qutenza is a TRPV1 channel agonist indicated for the management of neuropathic pain associated with postherpetic neuralgia (PHN). The capsaicin in Qutenza (capsaicin) 8% patch is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin is an agonist for the transient receptor potential vanilloid 1 receptor (TRPV1), which is an ion channel-receptor complex expressed on nociceptive nerve fibers in the skin. Topical administration of capsaicin causes an initial enhanced stimulation of the TRPV1-expressing cutaneous nociceptors that may be associated with painful sensations. This is followed by pain relief thought to be mediated by a reduction in TRPV1-expressing nociceptive nerve endings. Over the course of several months, there may be a gradual re-emergence of painful neuropathy thought to be due to TRPV1 nerve fiber reinnervation of the treated area.

Length of Authorization

Coverage will be provided for 3 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:
- 4 patches (1120 billable units) every 90 days

I. INITIAL APPROVAL CRITERIA

Qutenza may be considered medically necessary if the below conditions are met:

Management of neuropathic pain associated with postherpetic neuralgia (PHN)
- Patient is 18 years of age or older; AND
- Patient has postherpetic neuralgia that has persisted for at least 6 months following healing of herpes zoster rash; AND
- Documented baseline Numerical Pain Rating Scale (NPRS); AND
- Patient had an inadequate response (or contraindication) to ALL four of the following:
Qutenza® (capsaicin 8% patch)
Last review: July 28, 2020
Page 2 of 3

- Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine)
- Gabapentin
- Pregabalin
- Lidocaine 5% patch

Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
- Patient is 18 years of age or older; AND
- Documented baseline Numerical Pain Rating Scale (NPRS); AND
- Patient had an inadequate response (or contraindication) to ALL four of the following:
  - Tricyclic antidepressant (e.g., amitriptyline, nortripsyline, maprotiline, desipramine)
  - Gabapentin
  - Pregabalin
  - Lidocaine 5% patch

II. RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:
- Patient continues to meet criteria identified under INITIAL APPROVAL CRITERIA; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe application site reactions, hypertension; AND
- Patient has experienced an improvement in pain of at least 30% from baseline Numerical Pain Rating Scale (NPRS)

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postherpetic Neuralgia</td>
<td>Health care professional administration: Single, 60-minute application of up to four patches. May be repeated every three months or as warranted by the return of pain (not more frequently than every three months)</td>
</tr>
<tr>
<td>Diabetic Peripheral Neuropathy</td>
<td>Health care professional administration: single, 30-minute application on the feet of up to four patches. May be repeated every three months or as warranted by the return of pain (not more frequently than every three months)</td>
</tr>
</tbody>
</table>

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7336</td>
<td>Capsaicin 8% patch, per square centimeter: 1 billable unit = 1 cm²</td>
</tr>
</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10144-0928-xx</td>
<td>Qutenza 8% kit (1 patch)</td>
</tr>
<tr>
<td>10144-0929-xx</td>
<td>Qutenza 8% kit (2 patches)</td>
</tr>
</tbody>
</table>
Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B02.22</td>
<td>Postherpetic trigeminal neuralgia</td>
</tr>
<tr>
<td>B02.23</td>
<td>Postherpetic polyneuropathy</td>
</tr>
<tr>
<td>B02.29</td>
<td>Other postherpetic nervous system involvement</td>
</tr>
<tr>
<td>E11.40</td>
<td>Type 2 diabetes mellitus with diabetic neuropathy</td>
</tr>
<tr>
<td>E10.42</td>
<td>Type 1 diabetes mellitus with diabetic polyneuropathy</td>
</tr>
</tbody>
</table>

Review History

1. Added new FDA indication of Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
2. Added following criteria:
   - Patient is 18 years of age or older; **AND**
   - Documented baseline Numerical Pain Rating Scale (NPRS); **AND**
   - Patient had an inadequate response (or contraindication) to ALL four of the following:
     - Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine)
     - Gabapentin
     - Pregabalin
     - Lidocaine 5% patch
3. Added the following ICD-10 codes:
   - **E11.40** Type 2 diabetes mellitus with diabetic neuropathy
   - **E10.42** Type 1 diabetes mellitus with diabetic polyneuropathy

References