I. Medication Description
Naldemedine is an opioid antagonist that blocks opioid binding at the mu, delta, and kappa receptors. It also functions as a peripherally-acting mu-opioid receptor antagonist in tissues such as the gastrointestinal tract, thereby decreasing the constipating effects of opioids. It is available as an oral medication for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain.
The CNS penetration of naldemedine is expected to be negligible at the recommended dose levels, limiting the potential for interference with centrally-mediated opioid analgesia.

II. Position Statement
Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy
Coverage for Symproic is provided for the treatment of opioid-induced constipation when the following criteria are met:

- Member must be of age 18 years or older AND
- Member must have been receiving treatment with opioids narcotics for at least 4 weeks AND
- Member has not obtained adequate relief of narcotic-related constipation after a trial with two plan-preferred medications (laxative agents: stool softeners, osmotics, stimulants, bulk-forming agents) OR the following criteria have been met:
  - When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
  - At least one of the following is met:
    - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
    - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
    - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).

The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

30 tablets per each 30 days are available for coverage.

V. Coverage Duration

Coverage is provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug **AND**
- Opioid therapy has not been discontinued.

VII. Billing/Coding Information

Symproic is available as 0.2 mg tablets.

VIII. Summary of Policy Changes

10/11/2017: new policy

IX. References

2. Symproic (naldemedine) [Prescribing Information]. Florham Park, NJ: Shionogi Inc.; March 2017

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.