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Dear Sir or Madam:

On behalf of AstraZeneca, this letter is a formal request to the Panel supporting the National Comprehensive Cancer Network (NCCN) Guidelines for Supportive Care to review updated information for MOVANTIK® (naloxegol) Tablets.

Specific Changes:

- We respectfully request that the Panel Members consider the update to the naloxegol indication within the Adult Cancer Pain (PAIN-F) and the consideration of opioid-induced constipation (OIC) for inclusion within the Survivorship (SPAIN-A) Recommendations related to the Principals of Opioid Use in Long-Term Survivors.

FDA Status:

- The indication for naloxegol was revised by the FDA on August 1, 2017.
- Naloxegol is now indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, *including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.*
- A copy of the MOVANTIK Prescribing Information may be found at the following link: [MOVANTIK Prescribing Information](#)

Rationale:

- Overall, cancer survival rates are increasing,¹ making pain related to prior cancer or its treatment an important healthcare issue. A meta-analysis investigating the prevalence of pain in patients with cancer showed that approximately 40 percent of patients experience pain after curative cancer treatment.² This review was based on literature published from September 2005 to January 2014 in adult patients.
- A claims-based retrospective analysis of real world evidence conducted by AstraZeneca, supports the similarity in clinical utilization patterns of the use of opioids by patients with cancer and non-cancer pain.³ This data formed the basis for discussions with the FDA regarding the naloxegol label indication and has been accepted for poster presentation at the Palliative and Supportive Care in Oncology Symposium (Oct 27-28, 2017).
- OIC is a common and persistent side effect of opioid therapy and can last for the duration of treatment.^{4,5}
- This label update clarifies that adult patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation are included within the MOVANTIK indication to treat OIC in adult patients with chronic non-cancer pain.

Thank you for your consideration.

Sincerely,

Catherine Datto, MS, MD

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References:

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4. Paice JA, Portenoy R, Lacchetti C, et al. Management of chronic pain in survivors of adult cancers: American Society of Clinical Oncology Clinical Practice Guideline. *J Clin Oncol*. 2016;34:3325-3345.
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