

Positive Quality Intervention: Stomatitis Prophylaxis During Everolimus (Afinitor®) Therapy

Description of PQI: The purpose of this PQI is to identify patients initiating everolimus therapy and could benefit from stomatitis prophylaxis with a steroid mouthwash.

Background: Stomatitis is a significant complication associated with mTOR inhibition. In BOLERO-2¹ patients receiving everolimus/exemestane (EVE/EXE), all grade stomatitis was 67%; 25% Grade 2 and 8% Grade 3. The median time to Grade 2 or worse onset was 15.5 days. The incidence of new stomatitis (Grade \geq 2) plateaued at 6 weeks. In a meta-analysis, 89% of first stomatitis events occurred within 8 weeks. Topical steroids are used to treat aphthous ulcers; anecdotal use of topical steroid prophylaxis has been reported. A trial entitled SWISH² revealed prophylactic use of 0.5 mg/5 mL dexamethasone oral solution markedly decreased the incidence and severity of stomatitis in patients receiving EVE/EXE for metastatic breast cancer and should be considered a new standard of care in this setting.

PQI Process: Upon receipt of a new prescription for everolimus:³

- Identify if the patient may be a candidate for steroid rinse
- Contact the oncologist to obtain a prescription for mouthwash:
 - Dexamethasone 0.5 mg/5 mL solution - swish 10 mL for 2 minutes and spit out QID for initial 8 weeks *Do not eat or drink for 1 hour post mouth rinse*
- Follow up within 7 days of starting everolimus/steroid mouth rinse

Patient Centered Activities:

- Provide [Oral Chemotherapy Education \(OCE\)](#) sheet
- Encourage patients to use rinse on a scheduled regimen, four times per day
- Brush teeth with soft or extra soft tooth brush
- Advise patients to immediately report any signs or symptoms of mouth sore
- Patient Assistance: [NCODA Financial Assistance Tool](#)

References:

1. Rugo, HS, Seneviratne, L, Beck JT, et. Al. Prevention of everolimus-related stomatitis in women with hormone receptor-positive, HER2-negative metastatic breast cancer using dexamethasone mouthwash (SWISH): a single-arm, phase 2 trial. *The Lancet Oncology*. Vol 18, Issue 5; 654-662, May 01, 2017 [https://doi.org/10.1016/S1470-2045\(17\)30109-2](https://doi.org/10.1016/S1470-2045(17)30109-2).
2. Baselga J, et Al. Everolimus in Postmenopausal Hormone-Receptor-Positive Advanced Breast Cancer (BOLERO-2). *The New England Journal of Medicine*. Vol 366, No 6; 520-529. February 9, 2012. <https://www.nejm.org/doi/full/10.1056/nejmoa1109653>.
3. [Afinitor® \(everolimus\) \[package insert\]](#).