



## 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-2<sup>1</sup> 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 SWISH<sup>2</sup> 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. A follow-up study, Alliance MIST Trial, found that the prophylactic use of dexamethasone mouthwash before initiation of everolimus is not superior to reactive use of dexamethasone mouthwash if mouth pain develops. But does continue the support use in reactive use.<sup>3</sup>

**PQI Process:** Upon receipt of a new prescription for everolimus<sup>4</sup>

- Identify patients on everolimus or exemestane as they 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 for everolimus
- 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. Ruddy, Kathryn J., et al. "Dexamethasone to Prevent Everolimus-Induced Stomatitis (Alliance MIST Trial: A221701)." *Seminars in Oncology*, vol. 50, no. 1, 1 Feb. 2023, pp. 7–10. [www.sciencedirect.com/science/article/pii/S0093775423000015?via%3Dihub](http://www.sciencedirect.com/science/article/pii/S0093775423000015?via%3Dihub), <https://doi.org/10.1053/j.seminoncol.2023.01.001>. Accessed 11 Sept. 2023.
4. [Afinitor® \(everolimus\) \[package insert\]](#).

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