



## Positive Quality Intervention: Stomatitis Prophylaxis during Everolimus therapy

**Description of PQI:** Identify patients who are using everolimus (Afinitor®) and could benefit from stomatitis prophylaxis with a steroid mouthwash.

**Background:** Stomatitis is a significant complication associated with mTOR inhibition. In BOLERO-2 patients (pts) receiving everolimus/exemestane (EVE/EXE), all grade (Gr) stomatitis was 67%; 33% had Gr ≥ 2 and 8% Gr 3. The median time to ≥ Gr 2 onset was 15.5 days, the incidence of new stomatitis (Gr ≥ 2) plateaued at 6 wks. In a meta-analysis, 89% of first stomatitis events occurred within 8 wks. Topical steroids are used to treat aphthous ulcers; anecdotal use as prophylaxis has been reported.

A trial entitled SWISH revealed the following: Prophylactic use of 0.5 mg/5 mL dexamethasone oral solution markedly decreases the incidence and severity of stomatitis in patients receiving EVE/EXE for MBC and should be considered a new standard of care in this setting. Although stomatitis seems to only be studied in the breast cancer indication, it is reasonable to assume that prophylactic use of steroid rinse would be beneficial for all patients receiving everolimus.

**PQI process:** Upon receipt of a new prescription for Everolimus (Afinitor)

- Identify if the patient may be a candidate for steroid rinse
- Contact the oncologist to obtain a prescription for mouthwash:
  - SWISH Study used dexamethasone 0.5mg/5ml solution
  - Directions: swish 10ml for 2 minutes and spit out QID for initial 8 weeks

**Patient Centered Activities:**

- Patient Compliance
  - Encourage patients to use rinse on a scheduled regimen, four times per day
- Patient Adherence
  - Call patient within 7 days of starting everolimus/steroid mouth rinse. Confirm patient is taking medications properly.
  - Reinforce compliance and teaching points

**Important notice:** National Community Oncology Dispensing Association, Inc. (NCODA), has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



- Additional call backs as needed, including refill reminder call before supply runs out
  - At every dispense, reinforce compliance and teaching point
- Patient Education
- Provide Oral Chemotherapy Education Sheet
  - Advise patients to immediately report any signs or symptoms of mouth sores
  - If the patient vomits or misses a dose, do not double up. Resume regular dosing schedule (4 times/day)

**Key Interventional Data:**

SWISH study revealed the following:

Study	Stomatitis Grade (%)				
	All	1	2	3	4
<b>BOLERO-2 (total)</b>	67	34	25	8	0
<b>SWISH (at 8 weeks)</b>	19.8	17.4	2.4	0	0

- Directions: swish 10ml for 2 minutes and spit QID for initial 8 weeks

**Labs:** blood glucose

**Adverse events:** In SWISH: most common: rash [2%], hyperglycemia [2%], stomatitis [1%] and pneumonitis [1%]

**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)

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