



Positive Quality Intervention: Stomatitis

Description of PQI: Identify patients who are using Afinitor (everolimus) 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 \geq 2 and 8% Gr 3. The median time to \geq Gr 2 onset was 15.5 days, the incidence of new stomatitis (Gr \geq 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 recent 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
 - Potential contraindications may include diabetic patients
- Contact the oncologist to obtain a prescription for mouthwash:
 - SWISH Study used dexamethasone 0.5mg/5ml solution

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Key Discussion Points:

- SWISH study revealed the following:

Study	Stomatitis Grade (%)				
	All	1	2	3	4
BOLERO-2 (total)	67	34	25	8	0
SWISH (at 8 weeks)	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%]

Patient Centered Activities:

- Patient Compliance
 - Urge 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.
 - Additional call backs as needed, including refill reminder call before supply runs out
 - At every dispense, reinforce compliance and teaching points
- Patient Education
 - 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)

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