

# PALLIATIVE CARE PHARMACY PHAST PHACT



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## Palliative Care Pharmacy Team:

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If you have a topic you  
would like the pharmacy  
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## TODAY'S TOPIC:

### What's New in Palliative Care Medications Drug #4: Bremelanotide (Vylessi®)

#### Background:

[Bremelanotide \(Vylessi®\)](#) is a melanocortin receptor (MCR) agonist that nonselectively activates several receptor subtypes that improves hypoactive sexual desire disorder in women

- Initial US approval: 2019
- Available as: 1.74mg/0.3mL subcutaneous solution

#### Importance:

In a US national household survey of adult sexual behavior conducted in 1992, the overall prevalence of sexual dysfunction among women 18–59 years old was 43%. Palliative care providers should be aware of pharmacological options for hypoactive sexual desire disorder in premenopausal women.

#### Pharmacology:

MoA:	Bremelanotide is a melanocortin receptor (MCR) agonist that nonselectively activates several receptor subtypes with the following order of potency: MC1R, MC4R, MC3R, MC5R, MC2R. At therapeutic dose levels, binding to MC1R and MC4R is most relevant. Neurons expressing MC4R are present in many areas of the central nervous system (CNS)
ADME:	<ul style="list-style-type: none"><li>- A: Tmax: 1 hour</li><li>- M: Hydrolyses of the amide bond of the cyclic peptide</li><li>- E: T<sub>1/2</sub>: 2.7 hours</li></ul>
DIs:	Concomitant use naltrexone may result in naltrexone treatment failure

Key: MoA: Mechanism of Action; ADME: Absorption, Distribution, Metabolism, and Excretion; DI: Drug Interaction; Tmax: time until

max concentration; T ½: terminal half-life; Cmax: max concentration; AUC: area under the curve

## Other Clinical Points:

<b>Cls:</b>	<ul style="list-style-type: none"> <li>- Hypersensitivity</li> <li>- Cardiovascular disease</li> <li>- Uncontrolled hypertension</li> </ul>
<b>Warnings and Precautions:</b>	<ul style="list-style-type: none"> <li>- Transient blood pressure increases and heart rate reductions occurs with each dose; monitoring recommended; use not recommended in patients at high risk for cardiovascular disease</li> <li>- Focal hyperpigmentation of the face, gingiva, and breasts has occurred, and is more likely in patients with dark skin; discontinuation may be appropriate</li> <li>- Nausea commonly occurs with first dose and lessens with subsequent use; if persistent, may treat with antiemetics; discontinuation may be needed</li> </ul>
<b>Dosing:</b>	1.75 mg subQ in the abdomen or thigh once as needed at least 45 minutes prior to anticipated sexual activity; MAX, 1 dose/24 hours and 8 doses/month; optimal time for administration has not been fully established and may be individualized based upon experience and duration of effect
<b>ADRs:</b>	<ul style="list-style-type: none"> <li>- Dermatologic: Flushing (20.3%), Injection site reaction (13.2%)</li> <li>- Gastrointestinal: Nausea (40%), Vomiting (4.8%)</li> <li>- Neurologic: Headache (11.3%)</li> </ul>

Key: Cl: contraindications; ADRs: adverse drug reactions

## The Literature:

- [Womens Health \(Lond\). 2016 Jun;12\(3\):325-37.](#)  
**Bremelanotide for female sexual dysfunctions in premenopausal women: a randomized, placebo-controlled dose-finding trial.**
  - Methods: Patients randomized to receive placebo or BMT 0.75, 1.25 or 1.75 mg self-administered subcutaneously, as desired, over 12 weeks. Primary end point was change in satisfying sexual events/month. Secondary end points included total score changes on female sexual function index and female sexual distress scale-desire/arousal/orgasm.
  - Results: Efficacy data, n = 327. For 1.25/1.75-mg pooled versus placebo, mean changes from baseline to study end were +0.7 versus +0.2 satisfying sexual events/month (p = 0.0180), +3.6 versus +1.9 female sexual function index total score (p = 0.0017), -11.1 versus -6.8 female sexual distress scale-desire/arousal/orgasm total score (p = 0.0014). Adverse events: nausea, flushing, headache.

- Conclusion: “In premenopausal women with female sexual dysfunctions, self-administered, as desired, subcutaneous BMT was safe, effective, and well tolerated “

### **So... What does this all mean Jenn?**

- Bremelanotide joins flibanserin (Addyi®) as promising agents for hypoactive sexual desire disorder – but unfortunately bromelanotide can only be administered to premenopausal women. This may, or may not be, important to palliative care patients
- There is some promising data for bromelanotide. Take a look at this [review](#) for additional information

### **CLINICAL PEARL:**

**Bremelanotide is a melancortin receptor agonist approved in 2019 for treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder.**