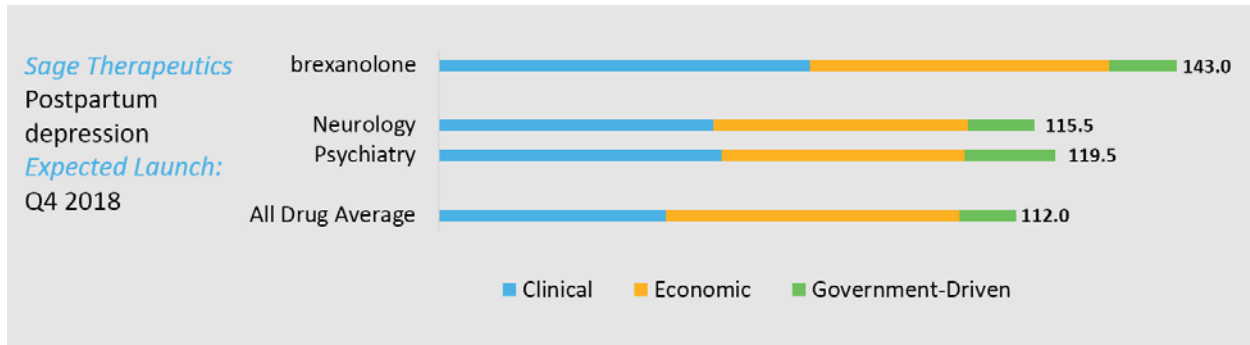


Example Drug Content: brexanolone



Sage Therapeutics' brexanolone, a first-in-class GABA-A modulator for treating postpartum depression, successfully addresses a number of key access criteria – in particular, a high unmet need (it would be the first approved drug for treating postpartum depression) – and a very limited duration of therapy, a single infusion, which means that payers won't be paying for the drug year-in and year-out. The drug wins additional points for getting FDA breakthrough status and a few more as medical-benefit drug – a status which makes controlling access more difficult for payers. And Sage will also benefit from strong support by effective women's health patient advocacy groups – payers will be wary of the negative press these groups can generate.

That's not to say brexanolone won't face some access challenges. Payers we've talked with are clearly watching this space – a probably expensive new therapeutic in a category where drug costs have not yet been significant. Not only does that mean they'll be passing on additional expense to their clients (absent recognizable and quantified cost-offsets), it also means payers have no good yardstick for forecasting the total cost impact of the drug. Nor can they be certain about value for money. In particular, payers will be worried that the drug will get widespread use in populations where it hasn't shown its greatest value. The drug works most dramatically in severe PPD patients, who hit the 3-point change in the Hamilton depression rating scale (HAM-D) that guidelines from the National Institute for Health and Clinical Excellence cite as clinically meaningful. But the drug could be approved for moderate PPD patients – and while those with moderate PPD improved, they didn't hit the 3 point mark. One other major uncertainty: was Sage's 30-day trial long enough to prove durability of effect?

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