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OPTIMUM

Optimizing Depression Treatment in Older Adults

INFORMATION FOR CLINICIAN PARTNERS

www.OPTIMUMstudy.org

Optimize your treatment with the OPTIMUM study.

What is Optimum?

OPTIMUM is a research study designed to test medications for older adults with depression suffering from treatment resistant depression. The study is designed to test which medications work best and are safest for older adults. Older adults with major depression that persists despite treatment with two or more antidepressants may be eligible.

How does OPTIMUM work?

1. **You recommend, we will screen**: you can refer your patients to us and we will screen for eligibility.
2. **We recommend, you prescribe:** we will ask the patient to sign a consent and then recommend you add aripiprazole, add bupropion, or switch to bupropion. You prescribe it.
3. **We guide, you prescribe:** we'll give you guidance about medication dosing based on how your patient is doing.
4. **We'll follow up:** we'll call your patient every two weeks for brief counselling to ask about symptoms and side effects. We will give you recommendations on dosages, staying the course, or stopping the medication.

Who is eligible?

Inclusion:

- Age 60 or older
- Treatment resistant depression defined by:

A. Major depression
B. PHQ-9 = 6 or greater
C. Two or more trials of antidepressant medications

Exclusion:

- Dementia
- Unstable medical illness
- Unable to take any of the OPTIMUM medications

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1

Step 1 (10 weeks): **Prescribe augmentation with aripiprazole or bupropion, or switch to bupropion**

At any time during Step 1, study clinician and patient may decide to move to Step 2 due to tolerability issues or lack of response.

2

Step 2 (10 weeks): For those who do not improve in Step 1, **prescribe augmentation with lithium or switch to nortriptyline**

3

All patients will be followed for 12 months.

Remission?
Enter continuation.

No remission?
Done with study.

Frequently Asked Questions (FAQ's)

What if I'm not sure whether a patient is eligible? Refer them to us and we'll sort it out. We offer informal consults including whether your patient may benefit best from OPTIMUM or another treatment.

What if a patient has a side effect or other problem? Report it to us and we will follow up. The study psychiatrists can provide clinical recommendations to you and your patient.

What study outcomes do we measure? We look at depressive symptoms, well-being, safety, falls, cognitive functioning, and mobility.

How will we be compensated for our time? Participants will be compensated $50 for the initial screening visit and $25 for each assessment visit after that. Clinicians will receive $1000 for each completed referral.

Prescribing Information

	Aripiprazole Augmentation	Bupropion switch/ Augmentation	Lithium Augmentation	Nortriptyline Switch
Starting Dose:	2.5mg	150mg*	300mg	25mg
Maximum Dose:	15mg	300mg	1200mg**	150mg***
Titration:	Study team recommends increases every 2 weeks (5, 7.5, 10, 15mg) based on symptoms and tolerability.	We will recommend increase to 300 mg after 4 weeks based on symptoms and tolerability.	Check blood level one week after initiating. Adjust dosage linearly to target 0.6 mEq/L. Recheck 1-2 weeks later. Adjust dose as needed to keep participant in 0.4-0.8 mEq/L window.	Increase by 25mg every 5-7 days until reaching 1mg per kg of body weight. Measure blood level after 5 -7 days. Adjust dose as needed to achieve therapeutic range of 80- 120 ng/mL.

*We will recommend an appropriate taper from current antidepressant for switch strategy prior to initiating bupropion.
**Study team ensure adherence and accuracy of blood level with patient prior to increasing Lithium beyond 600mg.
***Final dose will typically be 1mg/kg body weight.

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