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HELP YOUR ADULT PATIENTS WITH TARDIVE DYSKINESIA (TD)

# Take.



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#### THE SIMPLE CHOICE

#### Once-daily INGREZZA

is the simple choice to support patient adherence<sup>1,2,\*</sup>

#### SYMPTOM REDUCTION

INGREZZA 80 mg reduced uncontrolled movements in **7 of 10 patients at 6 weeks** (post hoc analysis)<sup>1,3,†</sup>

#### **SAVINGS & SUPPORT**

\$10 or less out-of-pocket is what most patients pay for INGREZZA<sup>4</sup>

\*Compared to once-daily regimens, timing adherence is 27% lower for twice-daily regimens, according to a meta-analysis of 51 studies in patients with chronic conditions.
¹Post hoc analysis included patients who had a baseline and a Week 6 AIMS total score. Reduction in uncontrolled movements as assessed by ≥1-point decrease in AIMS total score.







Visit INGREZZAHCP.com/Results to see how you can help your TD patients take control

#### Important Information

**INDICATION & USAGE** 

INGREZZA® (valbenazine) capsules is indicated for the treatment of adults with tardive dyskinesia.

#### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

#### **WARNINGS & PRECAUTIONS**

#### Somnolence

INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

#### QT Prolongation

INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

#### WARNINGS & PRECAUTIONS (continued)

#### Parkinsonism

INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

#### **ADVERSE REACTIONS**

The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >Placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call **1-800-FDA-1088**.

Please see the adjacent page for Brief Summary of Prescribing Information and visit Neurocrine.com/INGREZZAPI for full Prescribing Information.

**REFERENCES: 1.** INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc. **2.** Coleman CI, Limone B, Sobieraj DM, et al. Dosing frequency and medication adherence in chronic disease. *J Manag Care Pharm.* 2012;18(7):527-539. **3.** Data on file. Neurocrine Biosciences, Inc. **4.** Data on file as of Q1 2021. Neurocrine Biosciences, Inc. **5.** Data on file as of Q3 2021. Neurocrine Biosciences, Inc.



**Brief Summary:** for full Prescribing Information and Patient Information, refer to package insert.

#### INDICATION AND USAGE

INGREZZA® (valbenazine) capsules is indicated for the treatment of adults with tardive dyskinesia.

#### CONTRAINDICATIONS

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

#### WARNINGS AND PRECAUTIONS

#### Somnolence

INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA

#### QT Prolongation

INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. In patients taking a strong CYP2D6 or CYP3A4 inhibitor, or who are CYP2D6 poor metabolizers, INGREZZA concentrations may be higher and QT prolongation clinically significant. For patients who are CYP2D6 poor metabolizers or are taking a strong CYP3D6 inhibitor, dose reduction may be necessary. For patients taking a strong CYP3A4 inhibitor, reduce the dose of INGREZZA to 40 mg once daily. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

#### Parkingoniem

INGREZZA may cause parkinsonism in patients with tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. In the 3 placebo-controlled clinical studies in patients with tardive dyskinesia, the incidence of parkinson-like adverse events was 3% of patients treated with INGREZZA and <1% of placebo-treated patients. Postmarketing safety reports have described parkinson-like symptoms, some of which were severe and required hospitalization. In most cases, severe parkinsonism occurred within the first 2 weeks after starting or increasing the dose of INGREZZA. Associated symptoms have included falls, gait disturbances, tremor, drooling, and hypokinesia. In cases in which follow-up clinical information was available, parkinson-like symptoms were reported to resolve following discontinuation of INGREZZA therapy. Reduce the dose or discontinue INGREZZA treatment in patients who develop clinically significant parkinson-like signs or symptoms.

#### ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Hypersensitivity
- Somnolence
- QT Prolongation
- Parkinsonism

#### **Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Variable and Fixed Dose Placebo-Controlled Trial Experience

The safety of INGREZZA was evaluated in 3 placebo-controlled studies, each 6 weeks in duration (fixed dose, dose escalation, dose reduction), including 445 patients. Patients were 26 to 84 years of age with moderate to severe tardive dyskinesia and had concurrent diagnoses of mood disorder (27%) or schizophrenia/ schizoaffective disorder (72%). The mean age was 56 years. Patients were 57% Caucasian, 39% African-American, and 4% other. With respect to ethnicity, 28% were Hispanic or Latino. All subjects continued previous stable regimens of antipsychotics; 85% and 27% of subjects, respectively, were taking atypical and typical antipsychotic medications at study entry.

Adverse Reactions Leading to Discontinuation of Treatment

A total of 3% of INGREZZA treated patients and 2% of placebo-treated patients discontinued because of adverse reactions.

Common Adverse Reactions

Adverse reactions that occurred in the 3 placebo-controlled studies at an incidence of ≥2% and greater than placebo are presented in Table 1.

Table 1: Adverse Reactions in 3 Placebo-Controlled Studies of 6-week Treatment Duration Reported at ≥2% and >Placebo

Adverse Reaction <sup>1</sup>	INGREZZA (n=262) (%)	Placebo (n=183) (%)	
General Disorders			
Somnolence (somnolence, fatigue, sedation)	10.9%	4.2%	
Nervous System Disorders			
Anticholinergic effects (dry mouth, constipation, disturbance in attention, vision blurred, urinary retention)	5.4%	4.9%	
Balance disorders/fall (fall, gait disturbance, dizziness, balance disorder)	4.1%	2.2%	
Headache	3.4%	2.7%	
Akathisia (akathisia, restlessness)	2.7%	0.5%	
Gastrointestinal Disorders			
Vomiting	2.6%	0.6%	
Nausea	2.3%	2.1%	
Musculoskeletal Disorders			
Arthralgia	2.3%	0.5%	

<sup>&</sup>lt;sup>1</sup> Within each adverse reaction category, the observed adverse reactions are listed in order of decreasing frequency

Other Adverse Reactions Observed During the Premarketing Evaluation of INGREZZA

Other adverse reactions of ≥1% incidence and greater than placebo are shown below. The following list does not include adverse reactions: 1) already listed in previous tables or elsewhere in the labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, 4) which were not considered to have clinically significant implications, or 5) which occurred at a rate equal to or less than placebo.

Endocrine Disorders: blood glucose increased

General Disorders: weight increased

Infectious Disorders: respiratory infections

Neurologic Disorders: drooling, dyskinesia, extrapyramidal symptoms (non-akathisia)

Psychiatric Disorders: anxiety, insomnia

During controlled trials, there was a dose-related increase in prolactin. Additionally, there was a dose-related increase in alkaline phosphatase and bilirubin, suggesting a potential risk for cholestasis.

#### Postmarketing Experience

The following adverse reactions have been identified during post-approval use of INGREZZA that are not included in other sections of labeling. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drue exoosure.

Immune System Disorders: hypersensitivity reactions (including allergic dermatitis, angioedema, pruritis, and urticaria)

Skin and Subcutaneous Tissue Disorders: rash

#### **DRUG INTERACTIONS**

**Drugs Having Clinically Important Interactions with INGREZZA** 

Table 2: Clinically Significant Drug Interactions with INGREZZA

Table 2: Clinically Significant Drug Interactions with INGREZZA				
Monoamine Oxidase Inhibitors (MAOIs)				
Clinical Implication:	Concomitant use of INGREZZA with MAOIs may increase the concentration of monoamine neurotransmitters in synapses, potentially leading to increased risk of adverse reactions such as serotonin syndrome, or attenuated treatment effect of INGREZZA.			
Prevention or Management:	Avoid concomitant use of INGREZZA with MAOIs.			
Examples:	isocarboxazid, phenelzine, selegiline			
Strong CYP3A4 Inhibitors				
Clinical Implication:	Concomitant use of INGREZZA with strong CYP3A4 inhibitors increased the exposure (Cmax and AUC) to valbenazine and its active metabolite compared with the use of INGREZZA alone. Increased exposure of valbenazine and its active metabolite may increase the risk of exposure-related adverse reactions.			
Prevention or Management:	Reduce INGREZZA dose when INGREZZA is coadministered with a strong CYP3A4 inhibitor.			
Examples:	itraconazole, ketoconazole, clarithromycin			
Strong CYP2D6 Inhibitors				
Clinical Implication:	Concomitant use of INGREZZA with strong CYP2D6 inhibitors increased the exposure (C <sub>max</sub> and AUC) to valbenazine's active metabolite compared with the use of INGREZZA alone. Increased exposure of active metabolite may increase the risk of exposure-related adverse reactions.			
Prevention or Management:	Reduce INGREZZA dose when INGREZZA is coadministered with a strong CYP2D6 inhibitor.			
Examples:	paroxetine, fluoxetine, quinidine			
Strong CYP3A4 Inducers				
Clinical Implication:	Concomitant use of INGREZZA with a strong CYP3A4 inducer decreased the exposure of valbenazine and its active metabolite compared to the use of INGREZZA alone. Reduced exposure of valbenazine and its active metabolite may reduce efficacy.			
Prevention or Management:	Concomitant use of strong CYP3A4 inducers with INGREZZA is not recommended.			
Examples:	rifampin, carbamazepine, phenytoin, St. John's wort <sup>1</sup>			
Digoxin				
Clinical Implication:	Concomitant use of INGREZZA with digoxin increased digoxin levels because of inhibition of intestinal P-glycoprotein (P-gp).			
Prevention or Management:	Digoxin concentrations should be monitored when coadministering INGREZZA with digoxin. Increased digoxin exposure may increase the risk of exposure-related adverse reactions. Dosage adjustment of digoxin may be necessary.			

<sup>&</sup>lt;sup>1</sup> The induction potency of St. John's wort may vary widely based on preparation

#### $\label{lem:continuous} \textbf{Drugs Having No Clinically Important Interactions with INGREZZA}$

Dosage adjustment for INGREZZA is not necessary when used in combination with substrates of CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2C11, or CYP3A4/5 based on *in vitro* study results.

#### OVERDOSAGE

#### Human Experience

The pre-marketing clinical trials involving INGREZZA in approximately 850 subjects do not provide information regarding symptoms with overdose.

#### **Management of Overdosage**

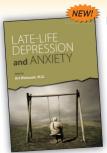
No specific antidotes for INCREZZA are known. In managing overdose, provide supportive care, including close medical supervision and monitoring, and consider the possibility of multiple drug involvement. If an overdose occurs, consult a Certified Poison Control Center (1-800-222-1222 or www.poison.org).

For further information on INGREZZA, call 84-INGREZZA (844-647-3992)



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# NEW TITLES in PSYCHIATRY

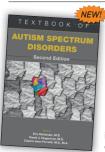


#### **Late-Life Depression and Anxiety**

Edited by Art Walaszek, M.D.

This book empowers health care professionals to accurately identify and diagnose anxiety and depression in older adult patients and help them find relief, stay independent, and lower their risk of suicide. The book discusses dependable assessment methods that consider multiple factors of mental health, including medical, behavioral, personal, social, and spiritual and provides guidance on culturally sensitive care to geriatric patients of diverse races, ethnicities, gender identities and sexual orientations, and intellectual abilities.

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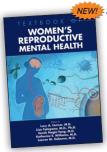
### Textbook of Autism Spectrum Disorders, Second Edition

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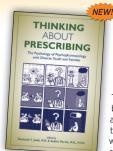
# Textbook of Women's Reproductive Mental Health

Edited by Lucy A. Hutner, M.D., Lisa A. Catapano, M.D., Ph.D., Sarah M. Nagle-Yang, M.D., Katherine E. Williams, M.D., and Lauren M. Osborne, M.D.

This is the first definitive guide to understanding, diagnosing, and treating the unique mental health needs of women and others who undergo female reproductive transitions during their reproductive lives. The book provides real-world insights into the mental, emotional,

and behavioral disturbances related to female reproductive stages—how these disorders present themselves, the underlying causes of specific conditions, and the latest evidence-based guidance for treatment.

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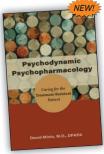
# Thinking About Prescribing The Psychology of Psychopharmacology With Diverse Youth and Families

Edited by Shashank V. Joshi, M.D., FAAP, DFAACAP, and Andrés Martin, M.D., M.P.H.

This volume makes the case for an ongoing alliance between psychopharmacotherapists, young patients, and their families. Chapters tackle issues ranging from the psychodynamics of medication use in adolescents with serious mental illness, the synergistic role of primary care providers and psychotherapists, engaging in patients, to prescribing via telemedicine. Readers will pick

psychoeducation with patients, to prescribing via telemedicine. Readers will pick up the foundational knowledge they need to develop a partnership with patients that is based on trust and candid communication—rather than on just the cold facts psychotropic medications.

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# **Psychodynamic Psychopharmacology**Caring for the Treatment-Resistant Patient

David Mintz, M.D.

This new guide emphasizes integrating research on evidence-based prescribing processes with psychodynamic insights and skills to enhance and optimize treatment outcomes with difficult-to-treat patients. The book examines the incidence and nature of pharmacological treatment resistance, exploring common psychodynamics that contribute to resistance and preparing readers to better understand and formulate the processes that interfere with the healthy use of medications.

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#### Geriatric Mental Health Care Lessons from a Pandemic

Edited by Robert P. Roca, M.D., M.P.H., Micheline Dugue, M.D., and Maria Llorente, M.D., FAPA

The effects of the COVID-19 pandemic on older adults have been well documented. In the case of older patients with mental illness, these challenges are magnified. The authors of this volume seek to share emerging practices that clinicians and systems can emulate. Introductory case vignettes, easily referenced key takeaways, and multiple-choice questions designed to reinforce learning offer

detailed descriptions of clinical and social innovations to mitigate the impact of the pandemic on older patients.

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#### **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies.
- Closely monitor all antidepressant-treated patients for clinical worsening, and emergence of suicidal thoughts and behaviors.
- Auvelity is not approved for use in pediatric patients.

Please see additional Important Safety Information and the Brief Summary of Prescribing Information on the following pages, including **Boxed Warning** for suicidal thoughts and behaviors.





(dextromethorphan HBr and bupropion HCI) extended-release tablets 45mg/105mg

Auvelity uses a new approach to treat MDD that is different from other oral antidepressants approved in more than 60 years<sup>1-3†</sup>



Auvelity is the first and only oral NMDA receptor antagonist for MDD<sup>1-3</sup>



# Symptom improvement at Week 1 and sustained at Week 6\*

 Patients taking Auvelity had significant change from baseline in the MADRS total score at Week 6 vs placebo (primary endpoint: LS mean change of -12.1 vs -15.9; P=0.002).<sup>1,4</sup>



#### Rapid remission starting at Week 2\*

 Significantly more patients achieved remission with Auvelity at Week 2 vs placebo (key secondary endpoint: 17% (24/142) vs 8% (12/159); P=0.013).<sup>4</sup>



# Demonstrated safety profile in controlled and open-label studies\*<sup>‡</sup>

- The most common adverse reactions in a 6-week study (≥5% and >2x placebo) were: dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction, and hyperhidrosis.¹
- Long-term safety up to 1 year in an open-label study was consistent with controlled studies.<sup>1,5-7</sup>



Explore the difference at AuvelityHCP.com

Actor Portrayal

\*GEMINI Phase 3 study evaluated Auvelity vs placebo in 327 patients (N=163 Auvelity and N=164 placebo) with MDD for 6 weeks. N denotes randomized patients. The mITT population, defined as all randomized patients who took at least 1 dose of study drug and had at least 1 post-baseline assessment, was n=156 Auvelity and n=162 placebo. Key secondary endpoints included change from baseline in MADRS total score at Week 1 (-7.2 Auvelity vs -5.0 placebo; P=0.007) and remission (MADRS total score ≤10) at Week 2. The safety population was n=162 Auvelity and n=164 placebo.

†The mechanism of action of Auvelity in the treatment of MDD is unclear.

‡COMET Phase 3 safety study assessed Auvelity up to 1 year in 876 MDD patients (roll-over from prior Auvelity studies and newly enrolled).

LS=least square; MADRS=Montgomery-Åsberg Depression Rating Scale; mITT=modified intent-to-treat; NMDA=N-methyl-D-aspartate

#### IMPORTANT SAFETY INFORMATION (CONT'D)

#### **CONTRAINDICATIONS**

**Seizure:** Do not use Auvelity in patients with a seizure disorder.

**Current or prior diagnosis of bulimia or anorexia nervosa:** A higher incidence of seizure was observed in such patients treated with bupropion.

Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs: Due to risk of seizure. Monoamine Oxidase Inhibitors (MAOIs): Do not use Auvelity concomitantly with, or within 14 days of stopping, an MAOI due to the risk of serious and possibly fatal drug interactions, including hypertensive crisis and serotonin syndrome. Conversely, at least 14 days must be allowed after stopping Auvelity before starting an MAOI antidepressant. Do not use Auvelity with reversible MAOIs such as linezolid or intravenous methylene blue.

Hypersensitivity: Do not use in patients with known hypersensitivity to dextromethorphan, bupropion, or any component of Auvelity. Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported with bupropion. Arthralgia, myalgia, fever with rash, and other serum sickness-like symptoms suggestive of delayed hypersensitivity have also been reported with bupropion.

#### **WARNINGS AND PRECAUTIONS**

Suicidal Thoughts and Behaviors in Pediatrics and Young Adults: Monitor all antidepressant-treated patients for any indication for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing Auvelity, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

<u>Seizure</u>: Bupropion, a component of Auvelity, can cause seizure and the risk is dose related. Because the risk of seizure with bupropion is dose-related, screen patients for use of other bupropion-containing products prior to initiating Auvelity. If concomitant use of Auvelity with other bupropion-containing products is clinically warranted, inform patients of the risk. Discontinue Auvelity and do not restart treatment if the patient experiences a seizure.

Increased Blood Pressure and Hypertension: Treatment with bupropion, a component of Auvelity, can cause elevated blood pressure and hypertension. The risk of hypertension is increased if Auvelity is used concomitantly with MAOIs or other drugs that increase dopaminergic or noradrenergic activity. Assess blood pressure before initiating treatment with Auvelity and monitor periodically during treatment. Monitor blood pressure, particularly in patients who receive the combination of bupropion and are receiving nicotine replacement.

Activation of Mania/Hypomania: Antidepressant treatment can precipitate a manic, mixed, or hypomanic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating Auvelity, screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder (e.g., family history of bipolar disorder, suicide, or depression). Auvelity is not approved for use in treating bipolar depression.

Psychosis and Other Neuropsychiatric Reactions: Auvelity contains bupropion and dextromethorphan. Depressed patients treated with bupropion have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment. Dextromethorphan overdose can cause toxic psychosis, stupor, coma, and hyperexcitability. Because the risks of neuropsychiatric reactions are dose-related, screen patients for use of other bupropion- or dextromethorphan-containing products prior to initiating Auvelity. If concomitant use of Auvelity with other bupropion- or dextromethorphan-containing products is clinically warranted, monitor patients for neuropsychiatric reactions and instruct patients to contact a healthcare provider if such reactions occur.

<u>Angle-Closure Glaucoma</u>: The pupillary dilation that occurs following use of many antidepressants, including Auvelity, may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including Auvelity, in patients with untreated anatomically narrow angles.

<u>Dizziness</u>: Auvelity may cause dizziness. Precautions to reduce the risk of falls should be taken, particularly for patients with motor impairment affecting gait or a history of falls. Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that Auvelity therapy does not affect them adversely.

Serotonin Syndrome: Auvelity contains dextromethorphan. Concomitant use with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk of serotonin syndrome, a potentially life-threatening condition. Prior to initiating therapy with Auvelity, screen patients for use of other dextromethorphan-containing products. If concomitant use of Auvelity with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome, and monitor for symptoms. Discontinue Auvelity and/or concomitant serotonergic drug(s) immediately if symptoms of serotonin syndrome occur and initiate supportive symptomatic treatment.

#### WARNINGS AND PRECAUTIONS (CONT'D)

Embryo-fetal Toxicity: Based on animal studies, Auvelity may cause fetal harm when administered during pregnancy. Discontinue treatment in pregnant females and advise the patient about the potential risk to a fetus. Use alternative treatment for females who are planning to become pregnant.



#### **DRUG INTERACTIONS**

**Strong Inhibitors of CYP2D6:** Concomitant use with Auvelity increases plasma concentrations of dextromethorphan. Dosage adjustment is necessary. Monitor patients for adverse reactions potentially attributable to dextromethorphan, such as somnolence and dizziness.

**Strong CYP2B6 Inducers:** Concomitant use with Auvelity decreases plasma concentrations of dextromethorphan and bupropion and may decrease efficacy of Auvelity. Avoid co-administration of Auvelity.

**CYP2D6 Substrates:** Concomitant use with Auvelity can increase the exposures of drugs that are substrates of CYP2D6. It may be necessary to decrease the dose of CYP2D6 substrates, particularly for drugs with a narrow therapeutic index.

**Digoxin:** Concomitant use with Auvelity may decrease plasma digoxin levels. Monitor plasma digoxin levels in patients treated concomitantly with Auvelity.

**Drugs that Lower Seizure Threshold:** Concomitant use with Auvelity may increase risk of seizure. Use Auvelity with caution. Discontinue Auvelity and do not restart treatment if the patient experiences a seizure.

Dopaminergic Drugs: Concomitant use with Auvelity can result in central nervous system toxicity. Use Auvelity with caution.

#### **USE IN SPECIFIC POPULATIONS**

**Lactation:** Because of the potential for neurotoxicity, advise patients that breast-feeding is not recommended during treatment with Auvelity and for 5 days following final dose.

**Renal Impairment:** Dosage adjustment is recommended in patients with moderate renal impairment (eGFR 30 to 59 mL/minute/1.73 m<sup>2</sup>). Auvelity is not recommended in patients with severe renal impairment (eGFR 15 to 29 mL/minute/1.73 m<sup>2</sup>). **Hepatic Impairment:** Auvelity is not recommended in patients with severe hepatic impairment.

#### ADVERSE REACTIONS

Most common adverse reactions (≥5% and twice the rate of placebo): dizziness (16%), headache (8%), diarrhea (7%), somnolence (7%), dry mouth (6%), sexual dysfunction (6%), and hyperhidrosis (5%).

Please see Brief Summary of Prescribing Information on the following pages, including **Boxed Warning** for suicidal thoughts and behaviors.

**AUV HCP ISI 08/2022** 

References: 1. Auvelity [Prescribing Information]. Axsome Therapeutics, Inc.: New York, NY 2. Thomas D, and Wessel C. The state of innovation in highly prevalent chronic diseases volume I: Depression therapeutics. December 2017. https://www.bio.org/sites/default/files/legacy/bioorg/docs/BIO\_HPCD\_Series-Depression\_2018-01-03.pdf. Accessed March 21, 2022. 3. FDA Depression Medicines. https://www.fda.gov/media/132665/download. Accessed March 21, 2022. 4. losifescu DV, Jones A, O'Gorman C, et al. Efficacy and safety of AXS-05 (dextromethorphan-bupropion) in patients with major depressive disorder: A phase 3 randomized clinical trial (GEMINI). *J Clin Psychiatry*. 2022;83(4):21m14345. 5. Data on File. AXS0080921. 6. Tabuteau H, Jones A, Anderson A, et al. Effect of AXS-05 (dextromethorphan-bupropion) in major depressive disorder: A randomized double-blind controlled trial. *Am J Psychiatry*. 2022;179(7):490-499. 7. Data on File. AXS0060921.

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AUVELITY™ (dextromethorphan Hbr-bupropion HCl) extended-release tablets, for oral use

#### **Brief Summary of Prescribing Information**

BEFORE PRESCRIBING AUVELITY, PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

#### **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

See full prescribing information for complete boxed warning.

- Antidepressants increased risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies.
- Closely monitor all antidepressant-treated patients for clinical worsening, and emergence of suicidal thoughts and behaviors.
- AUVELITY is not approved for use in pediatric patients.

#### INDICATIONS AND USAGE

AUVELITY is indicated for the treatment of major depressive disorder (MDD) in adults.

#### CONTRAINDICATIONS

**AUVELITY** is contraindicated in patients:

- · with a seizure disorder
- with a current or prior diagnosis of bulimia or anorexia nervosa as a higher incidence
  of seizures was observed in such patients treated with the immediate release formulation
  of bupropion
- undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- taking, or within 14 days of stopping, MAOIs due to the risk of serious and possibly fatal drug interactions, including hypertensive crisis and serotonin syndrome.
   Starting AUVELITY in a patient treated with reversible MAOIs such as linezolid or intravenous methylene blue is contraindicated.
- with known hypersensitivity to bupropion, dextromethorphan, or other components
  of AUVELITY. Anaphylactoid / anaphylactic reactions and Stevens-Johnson syndrome
  have been reported with bupropion. Arthralgia, myalgia, fever with rash, and other
  serum sickness-like symptoms suggestive of delayed hypersensitivity have also been
  reported with bupropion.

#### WARNINGS AND PRECAUTIONS

#### Suicidal Thoughts and Behaviors in Adolescents and Young Adults

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with MDD. The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1000 patients treated are provided in Table 1.

Table 1: Risk Differences of the Number of Patients of Suicidal Thoughts and Behavior in the Pooled Placebo-Controlled Trials of Antidepressants in Pediatric\* and Adult Patients

Age Range	Drug-Placebo Difference in Number of Patients of Suicidal Thoughts or Behaviors per 1000 Patients Treated	
	Increases Compared to Placebo	
<18 years old	14 additional patients	
18-24 years old	5 additional patients	
	Decreases Compared to Placebo	
25-64 years old	1 fewer patient	
≥65 years old	6 fewer patients	

<sup>\*</sup>AUVELITY is not approved for use in pediatric patients.

It is unknown whether the risk of suicidal thoughts and behaviors in children, adolescents, and young adults extends to longer-term use, i.e., beyond four months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with MDD that antidepressants delay the recurrence of depression and that depression itself is a risk factor for suicidal thoughts and behaviors.

Monitor all antidepressant-treated patients for any indication for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing AUVELITY, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

#### Seizure

Bupropion, a component of AUVELITY, can cause seizure. The risk of seizure with bupropion is

When a bupropion hydrochloride (HCI) sustained-release tablet was dosed up to 300 mg per day (approximately 1.5 times the maximum recommended daily dosage of AUVELITY), the incidence of seizure was approximately 0.1% (1/1,000) and increased to approximately 0.4% (4/1,000) at the maximum recommended dosage for the sustained-release tablet of 400 mg per day (approximately 2 times the maximum recommended daily dosage of AUVELITY). The risk of seizures is also related to patient factors, clinical situations, and concomitant medications that lower the seizure threshold. Consider these risks before initiating treatment

with AUVELITY. AUVELITY is contraindicated in patients with a seizure disorder, current or prior diagnosis of anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs. The following conditions can also increase the risk of seizure: severe head injury; arteriovenous malformation; CNS tumor or CNS infection; severe stroke; concomitant use of other medications that lower the seizure threshold (e.g., other bupropion products, antipsychotics, tricyclic antidepressants, theophylline, and systemic corticosteroids); metabolic disorders (e.g., hypoglycemia, hyponatremia, severe hepatic impairment, and hypoxia); use of illicit drugs (e.g., cocaine); or abuse or misuse of prescription drugs such as CNS stimulants. Additional predisposing conditions include diabetes mellitus treated with oral hypoglycemic drugs or insulin; use of anorectic drugs; and excessive use of alcohol, benzodiazepines, sedative/hypotics, or opiates.

Because the risk of seizure with bupropion is dose-related, screen patients for use of other bupropion-containing products prior to initiating AUVELITY. If concomitant use of AUVELITY with other bupropion-containing products is clinically warranted, inform patients of the risk. Discontinue AUVELITY and do not restart treatment if the patient experiences a seizure.

#### **Increased Blood Pressure and Hypertension**

AUVELITY contains bupropion, which can cause elevated blood pressure and hypertension. The risk of hypertension is increased if AUVELITY is used concomitantly with MAOIs or other drugs that increase dopaminergic or noradrenergic activity. Assess blood pressure prior to initiating treatment, and periodically monitor blood pressure during treatment with AUVELITY.

#### Activation of Mania/Hypomania

Antidepressant treatment can precipitate a manic, mixed, or hypomanic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating AUVELITY, screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder (e.g., family history of bipolar disorder, suicide, or depression). AUVELITY is not approved for use in treating bipolar depression.

#### **Psychosis and Other Neuropsychiatric Reactions**

AUVELITY contains bupropion and dextromethorphan. Depressed patients treated with bupropion have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. Some of these patients had a diagnosis of bipolar disorder. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment. Dextromethorphan overdose can cause toxic psychosis, stupor, coma, and hyperexcitability.

Because the risks of neuropsychiatric reactions are dose-related, screen patients for use of other bupropion- or dextromethorphan-containing products prior to initiating AUVELITY. If concomitant use of AUVELITY with other bupropion- or dextromethorphan-containing products is clinically warranted, monitor patients for neuropsychiatric reactions and instruct patients to contact a healthcare provider if such reactions occur.

#### Angle-Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs including bupropion, a component of AUVELITY, may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including AUVELITY, in patients with untreated anatomically narrow angles.

#### Dizzines

AUVELITY may cause dizziness. In controlled studies of AUVELITY, 14% of patients receiving AUVELITY and 6% of patients on placebo experienced dizziness. Take precautions to reduce the risk of falls, particularly for patients with motor impairment affecting gait or those with a history of falls. Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that AUVELITY therapy does not affect them adversely.

#### Serotonin Syndrome

AUVELITY contains dextromethorphan. Concomitant use of AUVELITY with SSRIs or tricyclic antidepressants may cause serotonin syndrome, a potentially life-threatening condition with changes including altered mental status, hypertension, restlessness, myoclonus, hyperthermia, hyperreflexia, diaphoresis, shivering, and tremor.

Prior to initiating AUVELITY, screen patients for use of other dextromethorphan-containing products. If concomitant use of AUVELITY with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome and monitor for symptoms. Discontinue AUVELITY and/or concomitant serotonergic drug(s) immediately if the above symptoms occur and initiate supportive symptomatic treatment.

#### **Embryo-fetal Toxicity**

Based on animal studies, AUVELITY may cause fetal harm when administered during pregnancy. In developmental toxicity studies in rats and rabbits, when a combination of dextromethorphan/quinidine was given to pregnant animals, fetal malformations (rabbits) and embryolethality were demonstrated in offspring. Neurotoxicity findings were observed in juvenile rats treated with a combination of dextromethorphan/quinidine on postnatal day (PND) 7, which corresponds to the third trimester of gestation through the first few months of life and may extend through the first three years of life in humans. The separate effect of dextromethorphan on developmental toxicity at the recommended clinical dose is unclear. Discontinue treatment in pregnant females and advise the patient about the potential risk to a fetus. Use alternative treatment for females who are planning to become pregnant.

#### ADVERSE REACTIONS

#### **Clinical Trials Experience**

AUVELITY was evaluated for safety in a total of 1114 patients with MDD or another indication from four studies (two 6-week studies in MDD, one 6-week study in another indication, and one long-term study in MDD and another indication). One 6-week study in MDD employed placebo as a control arm. Two 6-week studies, one in MDD and one in another indication, employed bupropion as a control arm. In the patients treated with AUVELITY in the long-term study (n=876), 597 received at least 6 months of treatment, and 110 received at least 12 months of treatment. The data below are based on the 6-week, placebo-controlled study in which either AUVELITY (n=162) or placebo (n=164) was administered twice daily to patients with MDD (Study 1).

#### Adverse Reactions Leading to Discontinuation

In the 6-week placebo-controlled study, 4% of patients treated with AUVELITY and 0% of placebo-treated patients discontinued participation due to adverse reactions. The adverse reaction that led to study discontinuation in ≥1% of patients treated with AUVELITY was anxiety (2%).

#### Most Common Adverse Reactions

In the 6-week placebo-controlled clinical study, the most common (incidence ≥5% for AUVELITY and more than twice as frequently as placebo) adverse reactions were dizziness (16%), headache (8%), diarrhea (7%), somnolence (7%), dry mouth (6%), sexual dysfunction (6%), and hyperhidrosis (5%).

Table 2: Adverse Reactions Occurring in  $\ge 2\%$  of Adult Patients with MDD Treated with AUVELITY and More Frequently than in Patients Treated with Placebo in a 6-Week Placebo-Controlled Study (Study 1)

Adverse Reaction	AUVELITY (N=162) %	Placebo (N=164) %
Dizziness	16	6
Nausea	13	9
Headache	8	4
Diarrhea	7	3
Somnolence	7	3
Dry mouth	6	2
Sexual dysfunction <sup>a</sup>	6	0
Hyperhidrosis	5	0
Anxiety	4	1
Constipation	4	2
Decreased appetite	4	1
Insomnia	4	2
Arthralgia	3	0
Fatigue <sup>b</sup>	3	2
Paraesthesia <sup>c</sup>	3	0
Vision blurred	3	0

<sup>°</sup>Sexual dysfunction includes orgasm abnormal, erectile dysfunction, libido decreased, anorgasmia

#### **DRUG INTERACTIONS**

Table 3: Clinically Important Drug Interactions with AUVELITY

Monoamine Oxi	dase Inhibitors (MAOIs)
Clinical Impact	The concomitant use of AUVELITY with MAOIs increases the risk of hypertensive crisis and serotonin syndrome.
Intervention	AUVELITY is contraindicated in patients taking MAOIs (including MAOIs such as linezolid or intravenous methylene blue) or in patients who have taken MAOIs within the preceding 14 days. Allow at least 14 days after stopping AUVELITY before starting an MAOI.
Serotonergic Dr	ugs
Clinical Impact	Concomitant use of AUVELITY with other serotonergic drugs increases the risk of serotonin syndrome.
Intervention	Monitor for symptoms of serotonin syndrome when AUVELITY is used concomitantly with other drugs that may affect the serotonergic neurotransmitter systems. If serotonin syndrome occurs, consider discontinuation of AUVELITY and/or concomitant serotonergic drugs.
Drugs that Lowe	r Seizure Threshold
Clinical Impact	AUVELITY contains bupropion which can cause seizure. Co-administration with other drugs that lower seizure threshold may increase risk of seizure.
Intervention	Use caution when administering AUVELITY concomitantly with drugs tha lower the seizure threshold. Discontinue AUVELITY and do not restart treatment if the patient experiences a seizure.
Strong Inhibitor	s of CYP2D6
Clinical Impact	Concomitant use of AUVELITY with strong CYP2D6 inhibitors increases plasma concentrations of dextromethorphan.
Intervention	Dosage adjustment is necessary when AUVELITY is coadministered with strong inhibitors of CYP2D6. Monitor patients for adverse reactions potentiall attributable to dextromethorphan, such as somnolence and dizziness.
Strong Inducers	of CYP2B6
Clinical Impact	Concomitant use of AUVELITY with strong CYP2B6 inducers decreases plasma concentrations of dextromethorphan and bupropion and may decrease efficacy of AUVELITY.
Intervention	Avoid co-administration of AUVELITY with strong inducers of CYP2B6. Consider alternatives to strong CYP2B6 inducers if needed.

Drugs Metabolized by CYP2D6		
Clinical Impact	CYP2D6 Substrates Coadministration of AUVELITY with drugs that are metabolized by CYP2D6 can increase the exposures of drugs that are substrates of CYP2D6.  Drugs that Require Metabolic Activation by CYP2D6 Drugs that require metabolic activation by CYP2D6 to be effective could have reduced efficacy when administered concomitantly with AUVELITY.	
Intervention	CYP2D6 Substrates  When used concomitantly with AUVELITY, it may be necessary to decrease the dose of CYP2D6 substrates, particularly for drugs with a narrow therapeutic index.  Drugs that Require Metabolic Activation by CYP2D6  Patients treated concomitantly with AUVELITY may require increased dose of dute that the require patients by CYP2D6 to be offertible.	
Digoxin	doses of drugs that require activation by CYP2D6 to be effective.	
Clinical Impact	Coadministration of AUVELITY with digoxin may decrease plasma digoxin levels.	
Intervention	Monitor plasma digoxin levels in patients treated concomitantly with AUVELITY and digoxin.	
Dopaminergic D	drugs	
Clinical Impact	CNS toxicity was reported when bupropion was co-administered with levodopa or amantadine. Adverse reactions have included restlessness, agitation, tremor, ataxia, gait disturbance, vertigo, and dizziness.	
Intervention	Use caution when administering AUVELITY concomitantly with dopaminergic drugs.	
Alcohol		
Clinical Impact	AUVELITY contains bupropion which can increase adverse neuropsychiatric events or reduce alcohol tolerance.	
Intervention	The consumption of alcohol should be minimized or avoided during treatment with AUVELITY.	

#### **USE IN SPECIFIC POPULATIONS**

#### Pregnancy

#### Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including AUVELITY, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or online at: https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/

#### **Risk Summary**

Based on animal studies, AUVELITY may cause fetal harm when administered during pregnancy. AUVELITY is not recommended during pregnancy. If a female becomes pregnant while being treated with AUVELITY, discontinue treatment and counsel the patient about the potential risk to a fetus.

#### **Clinical Considerations**

Disease-Associated Maternal and/or Embryo/Fetal Risk

Women who discontinued antidepressants during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressants. Consider the risks to the mother of untreated depression and potential effects on the fetus when discontinuing or changing treatment with antidepressant medications during pregnancy and postpartum.

#### Lactation

#### Risk Summary

Because of the potential for neurotoxicity, advise patients that breast-feeding is not recommended during treatment with AUVELITY and for 5 days following final dose.

#### **Renal Impairment**

Dosage adjustment of AUVELITY is recommended in patients with moderate renal impairment (eGFR 30 to 59 mL/minute/1.73 m²). The pharmacokinetics of AUVELITY have not been evaluated in patients with severe renal impairment. AUVELITY is not recommended in patients with severe renal impairment (eGFR 15 to 29 mL/minute/1.73 m²).

#### Hepatic Impairment

No dose adjustment of AUVELITY is recommended in patients with mild (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B). The pharmacokinetics of AUVELITY have not been evaluated in patients with severe hepatic impairment (Child-Pugh C). AUVELITY is not recommended in patients with severe hepatic impairment.

#### CYP2D6 Poor Metabolizers

Dosage adjustment is recommended in patients known to be poor CYP2D6 metabolizers because these patients have higher dextromethorphan concentrations than extensive/intermediate CYP2D6 metabolizers.

AUV HCP BS 08/2022

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<sup>&</sup>lt;sup>b</sup>Fatigue includes fatigue, lethargy

<sup>&</sup>lt;sup>c</sup>Paraesthesia includes paraesthesia, hypoaesthesia



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#### Assistant/Associate/Professor of Clinical Pediatric Psychiatry

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**Location**: Peoria, IL USA **Requisition ID**: 1014947 **Posting Close Date**: 4/19/2023

The University of Illinois College of Medicine at Peoria (UICOMP) seeks a Pediatric Psychiatry physician for a position at the level of Professor, Associate Professor or Assistant Professor to enhance an important clinical program.

Pediatric Psychiatry positions require candidates who are BC in Psychiatry and have completed 3 years in residency and 3 years in fellowship training in Pediatric Psychiatry. Candidates with scholarly and research interests are highly desirable, along with experience in teaching medical students and residents.

#### **Position Summary**

Provide outpatient diagnostic and management services for patients in the region with general Psychiatry needs and participate in undergraduate, graduate and continuing education programs of the Department.

#### **Duties & Responsibilities**

- Responsibilities Psychiatrist
- Participate in undergraduate, graduate and continuing education programs of the Department.
- Provide outpatient diagnostic and management services for patients in the region with general Psychiatry needs.
- Provide inpatient Psychiatry consultation for children.
- Organize and conduct research programs in Child Psychiatry.
- Perform other duties of a University faculty member including committee assignments, curriculum development, student counseling, and administration.

UICOMP is one of the regional campuses that make up the nation's largest public medical school. The Peoria campus is known among students for its small class sizes, rigorous curriculum and hands-on clerkships; to residents and fellows for the strong academic setting, large referral base and exceptional facilities; and by physicians seeking the ideal combination of teaching and practicing medicine in a research-based university setting.

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For fullest consideration please submit your application by 2/10/2023 at:

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#### AJP Audio and Video

In the March 2023 episode of our AJP Audio podcast, host Aaron van Dorn welcomes Gary S. Sachs, M.D., discussing his group's phase 3 clinical trial in which patients with major depressive disorder not responsive to antidepressant monotherapy alone reported reduced depressive symptoms with adjunctive cariprazine treatment, which had a favorable safety profile and was associated with a low discontinuation rate (Sachs et al., p. 241).

In an issue highlight video, AJP Deputy Editor Danny Pine discusses the articles "Functional Connectivity Mapping for rTMS Target Selection in Depression" (Elbau et al., p. 230) and "Adjunctive Cariprazine for the Treatment of Patients With Major Depressive Disorder: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study" (Sachs et al., p. 241).

### AJP CME

You can earn CME credits by reading articles in The American Journal of Psychiatry. Three articles in this issue form a short course that consists of reading the article and answering three multiple-choice questions with a single correct answer for up to 1 AMA PRA Category 1 Credit™ each. Credit is issued only to subscribers of the online AJP CME Course Program.

See the list below for articles in this month's issue that are the subject of a CME quiz.

#### In this issue

Moderate Alcohol Consumption and Depression: A Marginal Structural Model Approach Promoting Causal Inference (Visontay et al., p. 209)

Shared and Unique Changes in Brain Connectivity Among Depressed Patients After Remission With Pharmacotherapy Versus Psychotherapy (Dunlop et al., p. 218)

Functional Connectivity Mapping for rTMS Target Selection in Depression (Elbau et al., p. 230)



