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Learning Objectives

1. Identify the regional variances in prevalence, disease burden, health care utilization, and unmet needs for schizophrenia.
2. Distinguish the new and emerging therapies for schizophrenia, including clinical efficacy, safety, and adherence considerations.
3. Discuss managed care opportunities to support patients with schizophrenia to improve access, adherence, and health outcomes.

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Megan Ehret, PharmD, MS, BCPP *Faculty*	Consultant: Saladex Biomedical, LLC.
Vera Farkas Reinstein, PharmD, BCPS, FNCAP *Faculty*	Disclosed no relevant financial relationships.
Tracy McDowd, PharmD, FAMCP *Peer Reviewer*	Disclosed no relevant financial relationships.
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This activity is supported by an independent medical education grant from Bristol-Myers Squibb.

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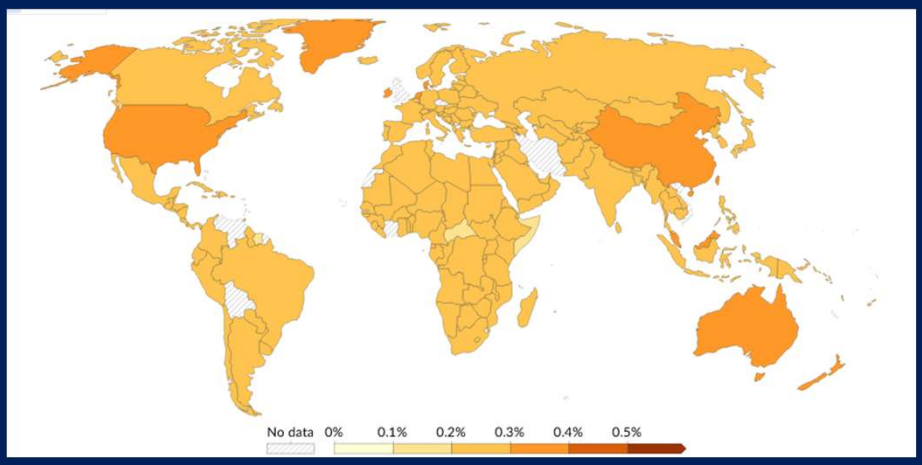
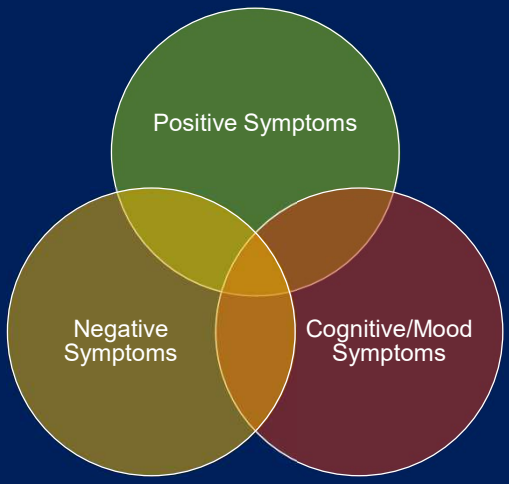
Schizophrenia

Schizophrenia Prevalence-2021



IHME, Global Burden of Disease (2024) – with major processing by Our World in Data; Creative Common License

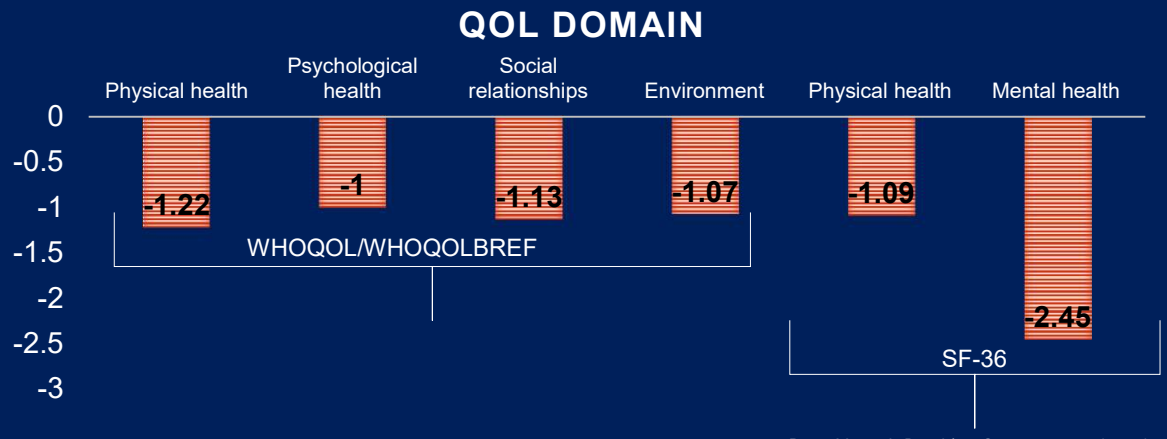
Schizophrenia



Grube BS, et al. Schizophre Res 1998;31:113-20.
Shafer A, et al. J Psychiatr Res 2019;115:113-20.

Quality of Life (QoL) in schizophrenia

WHOQOL: World Health Organization Quality of Life questionnaire
/WHOQOLBREF: brief version
SF-36: 36-item Short Form Health Survey to assess quality of life



Dong M, et al. *Psychiatr Q* **90**, 519–532 (2019)

Schizophrenia

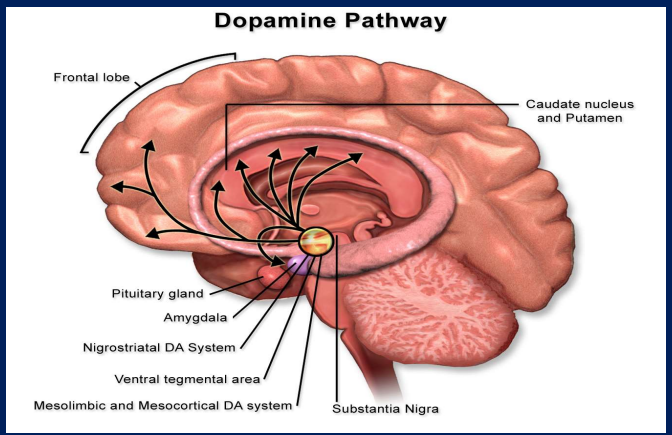
- Life-changing consequences
  - Social isolation
  - Stigma
  - Reduced prospects of finding a partner
- Reduced life expectancy (13-15 years)
  - Poor dietary habits
  - Weight gain
  - Smoking
  - Comorbid substance use

Jauhar S, et al. Lancet 2022;399:473-86.
Huorthøj C, et al. Lancet Psychiatry 2017;4:295-301.

Patient Testimonial Video

Pharmacotherapy of Schizophrenia

Dopamine Pathways and Beyond…



APA Schizophrenia Treatment Guidelines

- Pharmacotherapy:
  - Patients with schizophrenia should be treated with an antipsychotic medication; monitored for effectiveness and side effects
  - Evidence-based ranking of FGAs and SGAs- not possible
  - Patient-centered care, past responses, adverse effects, co-morbidities, drug-drug interactions, available formulations, pharmacokinetic considerations, cost

FGA = first-generation antipsychotic; SGA = second-generation antipsychotic

Keepers GA, Fochtmann LJ, Anzia JM, et al.
The American Psychiatric Association Practice Guideline
For the Treatment of Patients with Schizophrenia; Am J Psych;2020;177:868-872.

Antipsychotics

- First Generation
  - Chlorpromazine
  - Fluphenazine
  - Haloperidol
  - Loxapine
  - Perphenazine
  - Pimozide
  - Thioridazine
  - Thiothixene
  - Trifluoperazine
- Second Generation
  - Clozapine
  - Olanzapine
  - Risperidone
  - Paliperidone
  - Quetiapine
  - Aripiprazole
  - Ziprasidone
  - Iloperidone
  - Asenapine
  - Lurasidone
  - Brexpiprazole
  - Cariprazine
  - Pimavanserin*
  - Lumateperone

*not currently FDA-indicated for Schizophrenia

Long-Acting Injectable Antipsychotics

- Haloperidol Decanoate
- Fluphenazine Decanoate
- Risperidone Microspheres and Extended-Release
- Olanzapine Pamoate
- Paliperidone Palmitate
- Aripiprazole Monohydrate
- Aripiprazole Lauroxil

New and Emerging Treatments

Polling Question

Does your healthcare organization utilize long-acting injectable antipsychotic medications as first-line treatment options for patients with schizophrenia?

a) Yes
b) No
c) Unsure
d) Not applicable

New and Pipeline Long-Acting Injectable Antipsychotics

	Risperidone Extended-Release (Uzedy®)	Risperidone Extended-Release (Risvan®)	Risperidone Extended-Release (Rykindo®)	Paliperidone Palmitate Extended-Release (Erzofri®)	TV-44749
Route	Subcutaneous	Intramuscular	Intramuscular	Intramuscular	Subcutaneous
Frequency	Once monthly or every other month	Once monthly	Every two weeks	Once monthly injection	Once monthly
Oral Dose Equivalent	2-5/6 mg of oral risperidone	3 or 4 mg of oral risperidone	2-5/6 mg of oral risperidone		
Notes				One 351 mg dose on day one, then maintenance dose	Lack of PDSS?

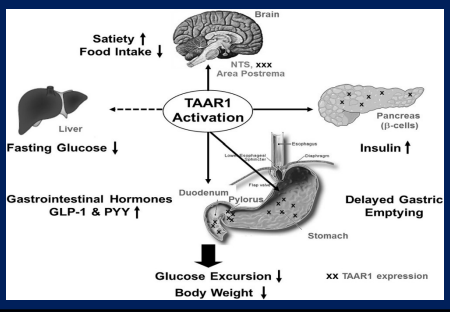
Uzedy [package insert]; Teva Neuroscience, Inc. 2024; Risvan [package insert]; Rovi Pharma Industrial Services. 2024. Rykindo [package insert]; Luye Pharmaceutical Co. 2023.; Erzofri [package insert]; Luye Pharmaceutical Co. 2024. Franzenburg KR. SOLARIS Protocol. Psych Congress 2023.

New/Pipeline Agents

Drug/Chemical Entity	Mechanism of Action	Clinical Trial Status
Ulotaront	Trace amine-associated receptor (TAAR) 1 agonist	Failed phase 3 trials
Ralmitaront	TAAR1 partial agonist	Failed phase 2 trials
Pimvanserin	5-HT2A receptor inverse agonist; 5-HT2C receptor antagonist	Currently approved: Treatment of hallucinations and delusions associated with Parkinson's disease psychosis
Roluperidone	Antagonist at 5-HT2A and sigma2 receptors	Complete Response Letter received: 2/27/24
Iclepertin	Potent and selective glycine transporter type 1 inhibitor	Phase 3 trials
Luvadaxistat	Selective inhibitor with a high binding affinity to d-amino acid oxidase	Phase 2 trials
Xanomeline and Trospium (KarXT)	Muscarinic acetylcholine receptor agonist at M1 & M4 receptors	PDUFA date: 9/26/24
TerXT; oral and LAI	Prodrugs of xanomeline and trospium	FDA 505(b)(2)
Emraclidine	Positive allosteric modulator that selectively acts on the M4 muscarinic receptor	Completing phase 2 trials
NBI-117568	M4 selective agonist	Entering phase 2 trials

Ulotaront

- Trace amine-associated receptor (TAAR) agonist: selectively activate trace amine receptors
- Partial agonist at 5-HT1a receptors (antidepressant and antianxiety effects)
- Potentially addressing cognitive impairments (i.e., attention and memory deficits)



https://commons.wikimedia.org/wiki/File:TAAR1_organ-specific_expression_and_function.jpg. Accessed: 8/2/24. Dedic N, et al. J Pharmacol Exp Ther 2019;371:1-14.

Other TAAR1 Partial Agonists Under Development

- RO06889450/ralmitaront

- TAAR1 full agonists: attenuate dopaminergic signaling
- Partial agonists: potentially normalize or increase dopaminergic signaling

RO6889450; Roche, Basel, Switzerland; NCT0366940; NCT04512066

Serotonin Receptor Antagonism/Inverse Agonism

- Pimvanserin
  - Potent 5-HT2A receptor inverse agonist (functional antagonist) & 5-HT2C receptor antagonist
  - Current research: adjunctive pimvanserin in stable outpatients with schizophrenia and predominant negative symptoms

- MIN-101/Roluperidone
  - Antagonist at 5-HT2A and sigma2 receptors
  - Phase 3 failed to meet prespecified primary outcome but did show a trend-level significance favoring roluperidone monotherapy on the primary endpoint

Pimvanserin [package insert]. Acadia Pharmaceuticals Inc; 2020.
Davidson M, et al. Am J Psychiatry 2017;174:1195-1202.

Glutamatergic Modulation

- BI 425809/Iclepertin
  - Potent and selective glycine transporter type I inhibitor
  - Demonstrated significant (d=0.34) improvements in cognition over 12 weeks of treatment in patients with schizophrenia (phase 2)
  - Phase 2: iclepertin added to current antipsychotic therapy and computer-based training for cognitive symptoms of schizophrenia
  - Phase 3: Add-on therapy with icelpertin are underway
- Sodium Benzoate
  - Phase 2/3 trials underway
  - TAK-831/luvadaxistat- not effective for negative symptoms but showed signal for improving cognitive symptoms

Fleischhacker WW, et al. Lancet Psychiatry 2021;8:191-201.
Huang CC, et al. Neurochem Res 2023;48:2066-76.

KarXT: Xanomeline and Trospium

Xanomeline	Trospium
• Crosses BBB • M1 receptor agonist • M4 receptor agonist	• Doesn't cross BBB • M1-M5 receptor • Antimuscarinic

- Increasing dopamine release in hippocampus and prefrontal cortex
- Decreasing dopamine release in substantia nigra, nucleus accumbens, and ventral striatum

Azargoonjahromi A. Clin Drug Investig 2024;44:471-93.

Xanomeline-trospium – ICER's evidence ratings

- xanomeline-trospium versus….

aripiprazole	• Insufficient
olanzapine	• Promising but inconclusive
risperidone	• Promising but inconclusive
no antipsychotic	• Promising but inconclusive

Xanomeline-trospium – ICER's Health Benefit Price Benchmarks

- Model assumptions (selected)
  - Population: adults with schizophrenia (not treatment-resistant)
- Xanomeline-trospium assumptions (selected)
  - Same risk of metabolic syndrome as the general population not taking antipsychotics
  - Same risk of tardive dyskinesia as second-generation antipsychotics

	Annual price at $100,000 threshold	Annual price at $150,000 threshold
QALy gained	$16,000	$19,000
evLY gained	$16,000	$20,000

QALy: quality-adjusted life year; evLY: equal value life year

Other Muscarinic Agents Under Development

- CVL-231/Emraclidine
  - Positive allosteric modulator that selectively acts on the M4 muscarinic receptor
  - EMPOWER-1 and EMPOWER-2: Patients who are experiencing an acute episode of psychosis
  - EMPOWER-3: Patients who have stable symptoms
- NBI-1117568
  - M4 selective agonist
  - Successful completion of a long-term preclinical toxicity program- support safe, chronic dosing

Cerevel Therapeutics Press Release. https://investors.cerevel.com/news-releases/news-release-details/cerevel-therapeutics-announces-positive-topline-results-cvl-231/. Accessed: 8/2/24
Neurocrine Biosciences, San Diego, CA, USA, NCT05545111

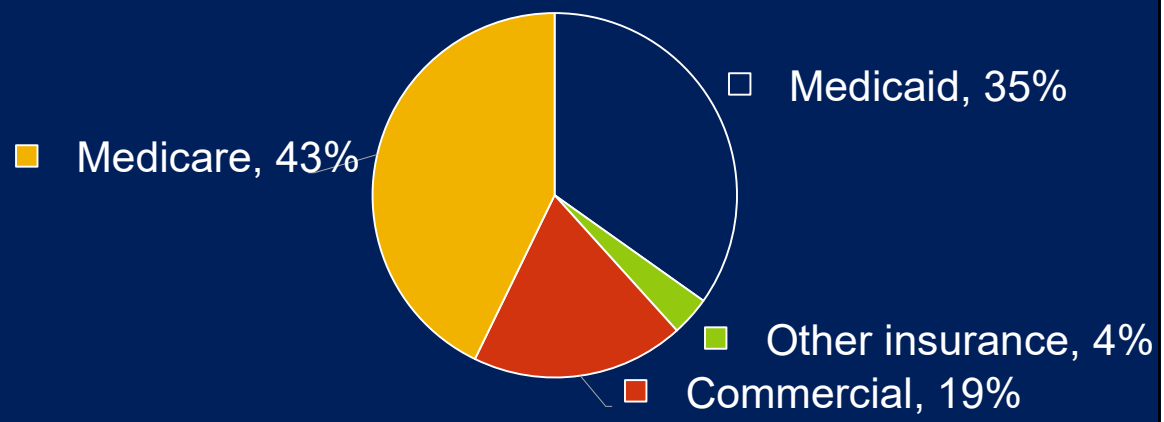
Managed Care Considerations

Schizophrenia
Managed Care Considerations

- **Epidemiology & Economic Impact**
- Quality Measures and Adherence
- Treatment Resistant Schizophrenia
- Managed Care Pharmacy Guidance

Covered Schizophrenia Lives

Medicare and Medicaid cover the majority of lives.



Geissler KH, et al. *JAMA Psychiatry.* 2023;80(3):278–279.

Economic Impact of Schizophrenia

- Affects <1% US population BUT ~2-4% prevalence in government program for low income (e.g. Medicaid)
- Costs are related to
  - ❖healthcare resource utilization
  - ❖non-healthcare related costs
    - ○ homelessness
    - ○ unemployment
    - ○ reduced work productivity
    - ○ premature mortality
    - ○ social services

Epidemiology of Schizophrenia

	Demographics			Race (%)			Coverage Type(%)	
	N	Mean age (years)	Female (%)	White	Black	Hispanic	Dual*	Managed Care plan
Total U.S.	688,437	48.2	43	42	27	12	44	67
NC	23,437	47.4	45	40	52	2	53	100
SC	9293	47.6	44	26	51	1	55	43

*Includes patients with Medicaid and Medicare eligibility

Incidence & prevalence higher in Medicaid compared to commercial population (2-fold/10-fold respectively in NYS vs national commercial employer database.

Patel et al. J Med Econ. 2022;51(1):792-807.
Finnerty et al Schizophr 10, 68 (2024).

Epidemiology

Annual Healthcare Utilization & Spend

	Healthcare Utilization			Mean Healthcare (HC) Cost (PPPY)		
	≥1 inpatient admission	≥1 ED visit	≥1 outpatient visit	Total HC cost	Medical cost	Pharmacy cost
Total U.S.	34%	45%	86%	$32,920	$25,908	$7,012
NC	31%	48%	92%	$24,029	$14,885	$9,144
SC	24%	59%	70%	$11,321	$8,797	$2,524

ED = emergency department, PPPY = per person per year

Patel et al. J Med Econ. 2022;51(1):792-807.

Schizophrenia
Managed Care Considerations

- Epidemiology & Economic Impact
- **Quality Measures and Adherence**
- Treatment Resistant Schizophrenia
- Managed Care Pharmacy Guidance

Quality

Readmission rates & follow-up care

Quality Measures	Readmission		Follow-up care	
	Inpatient readmission within 7 days*	Inpatient readmission within 30 days*	Antipsychotic dispensed within 30 days*	Outpatient visit within 30 days*
Total U.S.	8%	12%	14%	22%
NC	6%	9%	8%	22%
SC	5%	7%	9%	10%

*Data reported for patients with ≥1 all-cause inpatient admission

Patel et al. J Med Econ. 2022;51(1):792-807.

Quality

Antipsychotic Use –Medicaid focus

Quality Measures	Antipsychotic (AP) Use						Quality
	Any AP (%)	LAI (%)	OAP only (%)	Any SGA (%)	SGA LAI (%)	SGA OAP only (%)%	Adherent to any AP (%)
Total U.S.	51	13	39	46	9	36	56
US Medicaid	**82**	20	63	75	14	58	
NC	37	13	24	31	9	21	37
NC Medicaid	**69**	**22**	**47**	**60**	**16**	**42**	
SC	49	26	23	37	13	21	55
SC Medicaid	**86**	**40**	**46**	**72**	**24**	**42**	

AP = antipsychotic; OAP = oral antipsychotic; SGA = second generation

Patel et al. J Med Econ. 2022;51(1):792-807.

Adherence

Overview

•Prevalence varies, but some literature suggests >70% of patients with schizophrenia experience non-adherence

Risk factors for non-adherence	Healthcare (HC) impact of non-adherence
• Poor insight into disease • Lack of social support • Drug ineffectiveness • Drug-related adverse events	• Higher HC utilization (e.g. ED visits, inpatient admissions) • ↑ in HC spend by ~$20,700 per person per year

Desai et al. *J Manag Care Spec Pharm.* 2019;25(1):37-46.;Acosta et al. *World J Psychiatry.* 2012;2(5):74-82.; Pilon et al. *J Manag Care Spec Pharm.* 2021;27(7):904-914.

Adherence

Evidence for Long-acting injectable antipsychotics (LAIs)

- Study design: Systematic review and meta-analysis of 25 studies
- Study inclusion criteria (selected): adults with schizophrenia
- Patients initiated on a LAI were 89% **more likely to be adherent** to their medication compared to those initiated on an oral antipsychotic (Odds ratio [OR]: 1.89, 95% confidence interval [95% CI]: 1.52 to 2.35)
- LAIs were associated with higher pharmacy costs that were **mostly offset** by lower medical costs (driven by decreased hospitalizations)

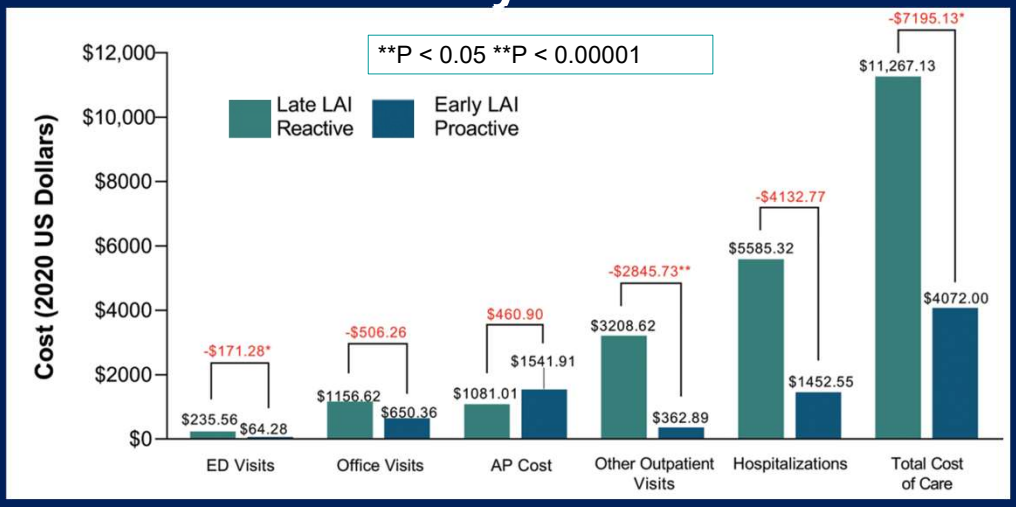
Lin et al. *CNS Drugs.* 2021;35(5):469-481.

Adherence, HC utilization and Costs of LAI and PO Antipsychotics in SC Medicaid

- LAIs compared to OAPs were associated with
  - ↑ treatment adherence
  - ↓ outpatient care costs coupled with OAPs
  - ↓ total non-drug costs, including inpatient/ ED /outpatient visits
- All cause costs higher in LAI cohort ~$26K vs ~$17K driven by difference in medication costs. (COSTS pre-rebate, 3 yr time)
- Given higher costs of LAIAs, must assess the VALUE into benefit design

Cai et al J Managed Care Sec Pharm 2024

Schizophrenia-Related Healthcare Utilizations with Early and Late LAI Use



Early LAI: first[a] LAI claim ≤1 year after index date.
Late LAI: first LAI claim >1 year after index date.
Proactive: no schizophrenia-related hospitalization or ED visit before LAI initiation
Reactive: schizophrenia-related hospitalization or ED visit prior to LAI initiation

Kane JM, et al. International Clinical Psychopharmacology. 2023; 38(4): 240-248

LAI Barriers and Solutions

SELECTED Challenges and Opportunities

Patient Refusal	Misunderstand Tolerability
• Perceived coercion/loss of autonomy • Negative stigma • Fear of needles	• Both patient and clinician • Injection site reactions (ISR) • Worse side effect burden than by mouth
• EDUCATION • Shared Decision Making • Caregiver/family involvement	• Same as on left • Minimal temporary ISR • SGA ↓ painful than FGA • FGA ↑EPS incidence • LAI SE less than PO

Adherence Support

Community Pharmacy's Vital Role

- Critical for schizophrenia population (not reimbursed)
  - Adherence Packaging
  - Med Synchronization
  - Free Delivery
  - LAI antipsychotic administration (on-site, at home)
  - Clozapine support
    - REMs registered
    - Stock product
    - ANC POC testing
- Metabolic Monitoring, DM Screening Potential
- Tobacco Cessation Counseling Support

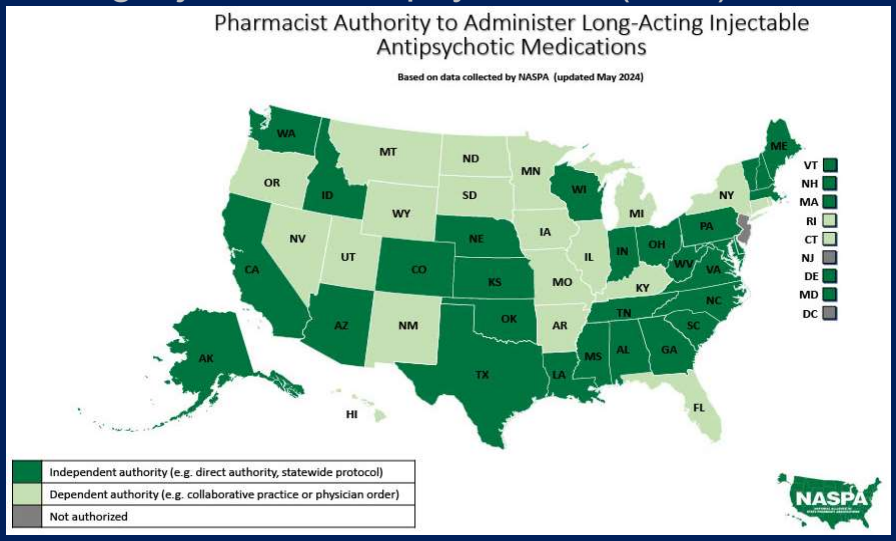
Access to Care

Challenges and Opportunities

Geography	Healthcare Literacy	Insurance
Urban vs Rural	Patient understanding Counseling and Education	Lack of insurance Prior authorizations
telemedicine funded community pharmacy support	case management community pharmacy support	Medicaid expansion barrier free pharmacy benefit design

Access to Care & Adherence Support

Long-acting injectable antipsychotics (LAIs)



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Schizophrenia
Managed Care Considerations

AMCP

- Epidemiology & Economic Impact
- Quality Measures and Adherence
- **Treatment Resistant Schizophrenia**
- Managed Care Pharmacy Guidance

AMCP

Treatment Resistant Schizophrenia (TRS)

Overview

Prevalence of TRS	Predictors of TRS	Impact of TRS
20 - 50%	• Early onset • Negative symptoms • Rural upbringing	• ↓ QOL • ↑ Non-adherence • ↑ Risk suicidal behavior • ↑↑↑ Cost (3-11X more than in remission)

Wander. *Am J Manag Care.* 2020;26(3 Suppl):S62-S68.; Smart et al. *Psychol Med.* 2021;51(1):44-53.
Nucifora et al Neurobiol Dis. 2019 Nov; 131: 104257.

Polling Question

My organization pays pharmacists an injection administration fee to administer LAIs

a) Yes
b) No
c) Unsure

Treatment Resistant Schizophrenia

CLOZAPINE Role

- FDA-approved atypical antipsychotic medication for TRS
- APA (2020 Schizophrenia Treatment Guidelines) recommends (1B) that patients with TRS be treated with clozapine.
- Treatment Resistance = tried and failed 2 antipsychotic medications at adequate dose and duration (AND adherence)
- Broader effects: evidence for efficacy in suicidality, aggression and substance misuse
- ↓ risk of suicide (even in non-TRS) , tardive dyskinesia & relapses
- Improves cognition
- Delay of several years typical before patients started on clozapine

Keepers et al. Am J Psychiatry . 2020 Sep 1;177(9):868-872;
Kelly et al. Psychiatr Serv. 2018 Feb 1; 69(2): 224–227.

Clozapine Prescribing Rates Vary 13-fold in US Medicaid Patients

Rate of prescriptions per 10,000 enrollees

- SD **191.6** NC 62.5 SC- 20.2 AR:14.8
- Black Americans were less likely to be prescribed clozapine
- BEN = benign ethnic neutropenia in 25-40% African ancestry, up to 35% of Middle Eastern descent
- PLAN: provider education, support POC testing (ANC & levels)

Benito et al Schizophr Res. 2023 May:255:79-81.

Treatment Resistant Schizophrenia

Role of & barriers associated with clozapine

- Despite APA recommends that patients with TRS be treated with clozapine (level 1B) –utilization well below expected rate 20-30%
- Barriers associated with clozapine utilization:

Frequency of monitoring	Side effect profile	Clinician unfamiliarity	Adherence	Healthcare resources

- Patients using **clozapine** showed lowest nonadherence (4.77%), even lower than non-adherence with **LAIs (vs POs)** 7% vs 10%)

Keepers et al. Am J Psychiatry. 2020;177(9):868-872; Farooq et al. BJPsych Bull. 2019;43(1):8-16; Lieslehto et al. Schizophrenia Bulletin. May 2022.

Treatment Resistant Schizophrenia

Strategies for addressing barriers to clozapine

- EDUCATION - provider and patient education

- POC lab testing (provider and pharmacy)
- Multidisciplinary care
  - Clozapine Clinics
  - Pharmacy
    - adherence support – packaging, med synch/delivery
    - monitor adherence-LAIA access-earlier TRS identification/earlier access to clozapine
    - ANC testing
    - GASS clozapine questionnaire tool -constipation support
- REMS re-evaluation (Nov 2024) –loosen burden?

Schizophrenia
Managed Care Considerations

Formulary Considerations

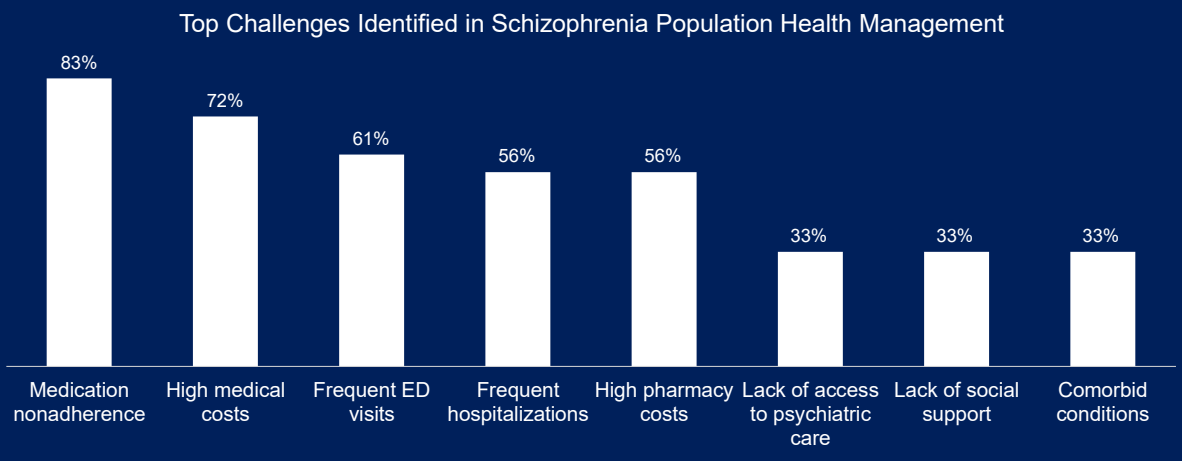
Perspectives from formulary decision makers

- Perspectives from formulary decision makers deep dive – Roach et al., Journal of Managed Care Pharmacy, 2021.
  - Study design: observational study using interviews and web-based surveys
  - Study objective: elicit challenges and best practices in schizophrenia population health management
  - Data source: 18 physicians and pharmacists representing >104 million covered lives

Roach M, et al. *J Manag Care Spec Pharm*. 2021;27(10-a):S2-S13

Formulary Considerations

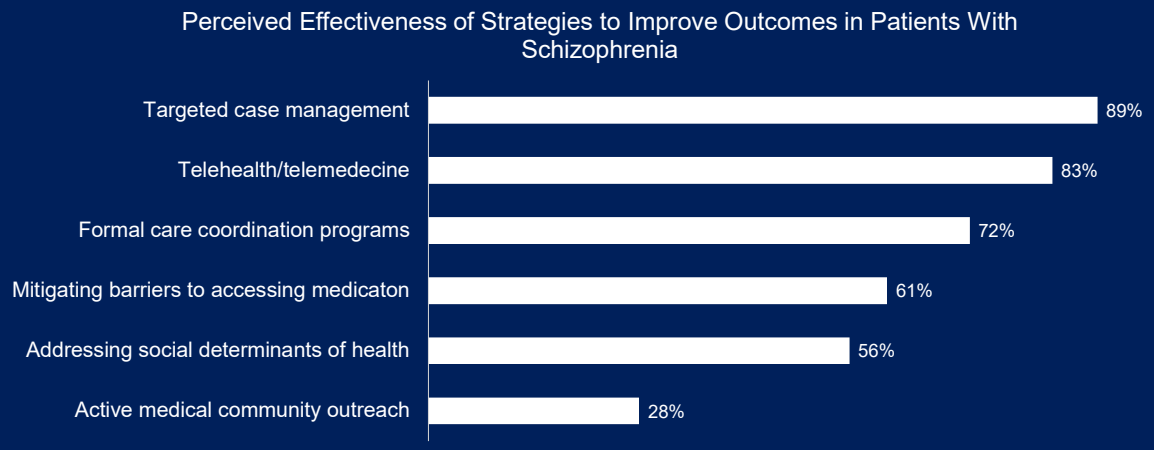
Perspectives from formulary decision makers



Roach M, et al. *J Manag Care Spec Pharm*. 2021;27(10-a):S2-S13

Formulary Considerations

Perspectives from formulary decision makers



Roach M, et al. *J Manag Care Spec Pharm*. 2021;27(10-a):S2-S13

Best Antipsychotic

- The one the patient will take
  - People respond differently
  - Side effect consideration (whole person approach)
  - Shared decision making (FEP programs)
  - Coverage issues/higher copays (less with govt programs)
- Other considerations
  - SGAs over FGAs due to initial side effect profile
  - LAI benefit
  - Clozapine: treatment resistant schizophrenia; suicidality; aggression
  - Polypharmacy only if residual symptoms & other causes ruled out*

*Lahteenvuo Drugs 2021; 81(11): 1273–1284.

Managed Care Pharmacy Guidance

- NO treatment algorithm
- Limitations with comparative effectiveness data
- Eliminate LAI antipsychotic barriers (steps, ↑copays) to promote earlier access and adherence
- Improve clozapine utilization
- Community pharmacy partnership
  - LAI admin (waste-free!) & clozapine
  - Whole health support: Tobacco cessation, DM, HTN, POC testing
  - QUALITY MEASURES BEYOND PDC

Questions

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Scan the QR code for further instructions on how to claim CPE and access the handout.

FACULTY BIOGRAPHY

Megan Ehret, PharmD, MS, BCPP **Professor and Co-Director** **Mental Health Program** **University of Maryland, School of Pharmacy**	Dr. Ehret is a graduate of the University of Toledo where she completed her PharmD degree, and she went on to complete a Psychiatric Pharmacy Residency. She then completed a Psychopharmacology and Pharmacogenomics Fellowship at Nova Southeastern University. After training, she received her initial faculty appointment at the University of Connecticut and gained tenure during her stay there. Currently, her role is a Professor and Co-Director of the Mental Health Program at the University Of Maryland School Of Pharmacy. She has the privilege of working with the State of Maryland Medicaid in evaluating antipsychotic use. She is a Past-President of AAPP and is the current BCPP Recertification Director. Dr. Ehret has worked with the State of Maryland to establish regulations permitting community pharmacists the authority to administer maintenance injections. Dr. Ehret has publications and book chapters describing psychotropic medication adherence and the role of pharmacogenomics in medication selection.

FACULTY BIOGRAPHY

Vera F. Reinstein, PharmD, BCPS **Clinical Pharmacist** **Alliance Health**	Dr. Vera Farkas Reinstein is the Clinical Pharmacist with Alliance Health, the public behavioral health services managed care organization (MCO) for Medicaid and uninsured consumers in the North Carolina counties of Wake, Johnston, Harnett Cumberland, Orange, Durham and Mecklenburg. Dr. Reinstein is a proud gator, having earned her Doctor of Pharmacy degree at the University of Florida and completed her pharmacy residency at the Moses H. Cone Memorial Hospital in Greensboro. She has been credentialed as a Board Certified Pharmacotherapy Specialist since 1994. Dr. Reinstein has practiced in various settings including academia with ambulatory care geriatric focus, industry, and hospitals, which included Ambulatory Care in the VA in Florida. From 2010-2016, Dr Reinstein worked with Community Care of North Carolina (CCNC) at Duke University's Division of Community Health supporting the Medicaid Case Management Program for a 5-county area. In her current role since 2016 with Alliance, she provides to Alliance staff and community partners psychiatric pharmacotherapy education and support though consultation to Alliance care management. Her roles with Alliance include improving access to medications for opioid use disorder (MOUD) and naloxone, to underutilized evidence-based therapies such as clozapine and long-acting injectable antipsychotics and working with community pharmacies.