

The Business and Operations of Long Acting Injectable Medications

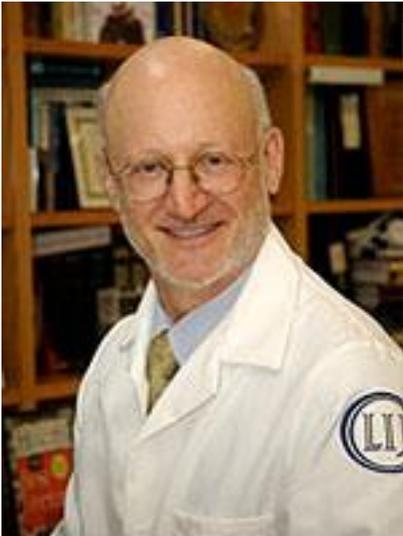
The Care Transitions Network

National Council for Behavioral Health
Montefiore Medical Center
Northwell Health
New York State Office of Mental Health
Netsmart Technologies



for People with Serious Mental Illness

Please welcome our presenters



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Webinar Objectives

- Healthcare administrators rightly jump to the logistics of any new intervention:
 - What will this cost and how will it be paid for?
 - What impact will this have on staff?
 - On our workflows?
 - On contracts?
- Part 3 of this webinar series on LAI medications will help healthcare administrators understand and navigate payer benefit and authorization policies, achieve operational efficiencies and overcome practical barriers to implementation.

Outline

Patient Specific Benefit Verification

- Factors affecting coverage
- Payer Types
- Obtaining the LAI
- Benefit Category
- Site of Service
- Coding for Reimbursement

Steps to Implementing LAI treatment service

- Education
- Implementation
- Evaluation
- Success factors for adherence clinics

Patient-Specific Benefit Verification

Determine Patient-Specific Benefit Verification

- Coverage for LAIs varies and may differ from coverage for oral medications.
- Thoroughly research a patient's health insurance plan or plans and the prescription coverage before an LAI is ordered or prescribed.
- Determine the patients' deductible and how much more must be met.
- Confirm whether the patient can afford the remaining deductible and copayment/coinsurance.
- If not covered by insurance, explore patient assistance programs.
- We strongly recommend that prescriber time not be used for obtaining authorization.
 - Use of clerical staff for this activity is much more cost effective.

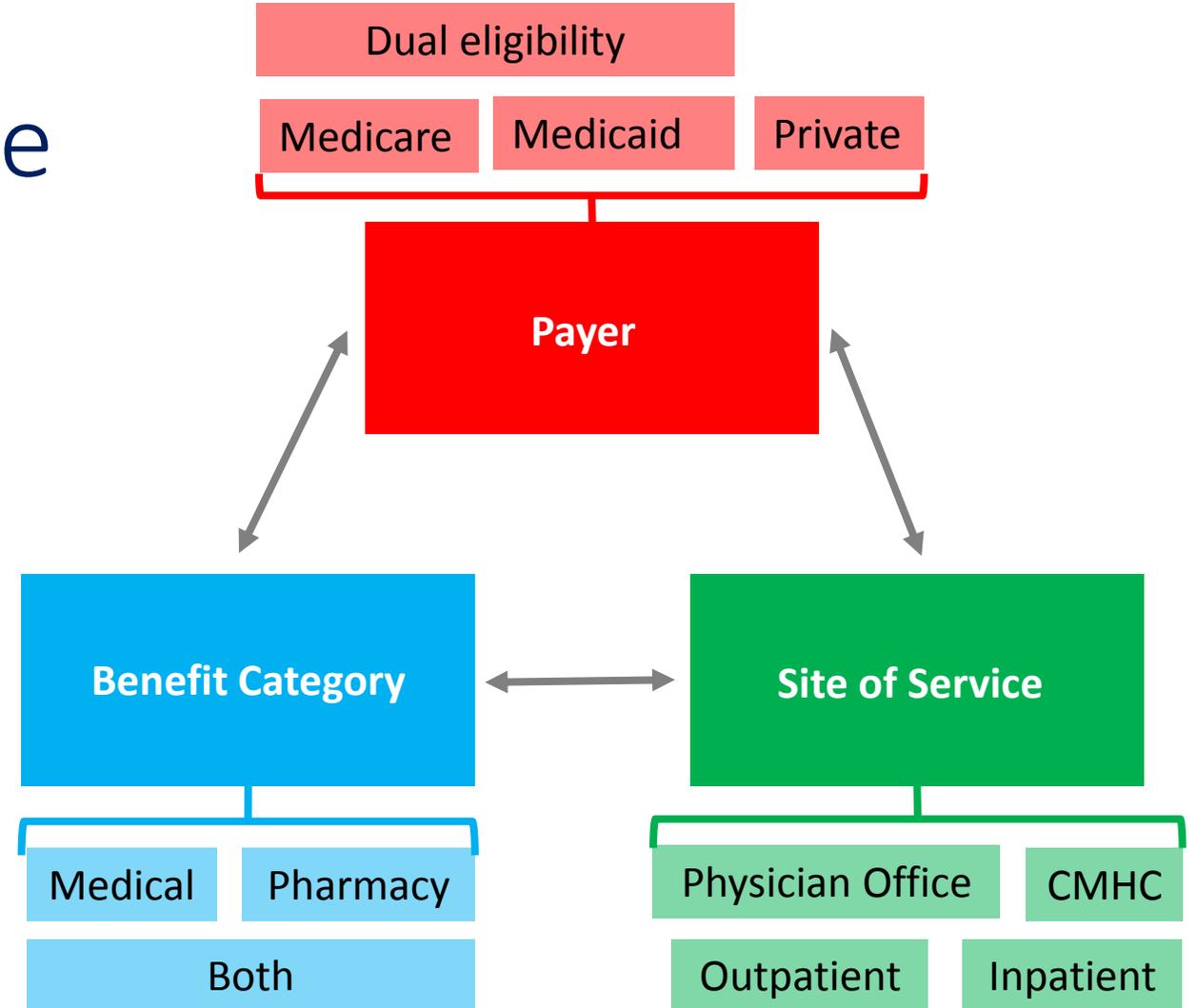
Benefit verification: Factors affecting coverage

- Check coverage
 - Is the benefit category medical or pharmacy?
 - Is the LAI not on formulary and if so is there a formulary exception process?
- Determine Access
 - Does the LAI require prior authorization?
 - Does the patients meet the payers necessary requirements for use of the LAI?
 - Are there quantity limits to what is covered?
- Product acquisition
 - What are the payers requirements for obtaining the LAI? Buy and bill? Specialty pharmacy? Retail pharmacy?
- Patient cost-sharing
 - Co-pay or Co-insurance? Ask about patient's cost-sharing obligations and whether they vary by benefit category or site of care.
- Site of care classification
 - What is the site of care? Identify the site of care and determine how the payer classifies the site

Factors Affecting Coverage

- Type of Payer
 - Medicaid
 - Medicare
 - Private payer (including State Health Insurance Marketplace)
- Benefit Category
 - Medical benefit
 - Pharmacy benefit
- Site of Service
 - Physician office
 - Community Mental Health Clinic
 - Partial hospitalization
 - Outpatient
 - Inpatient

**The Benefit Category and Site of Service influence how the LAI is obtained.*



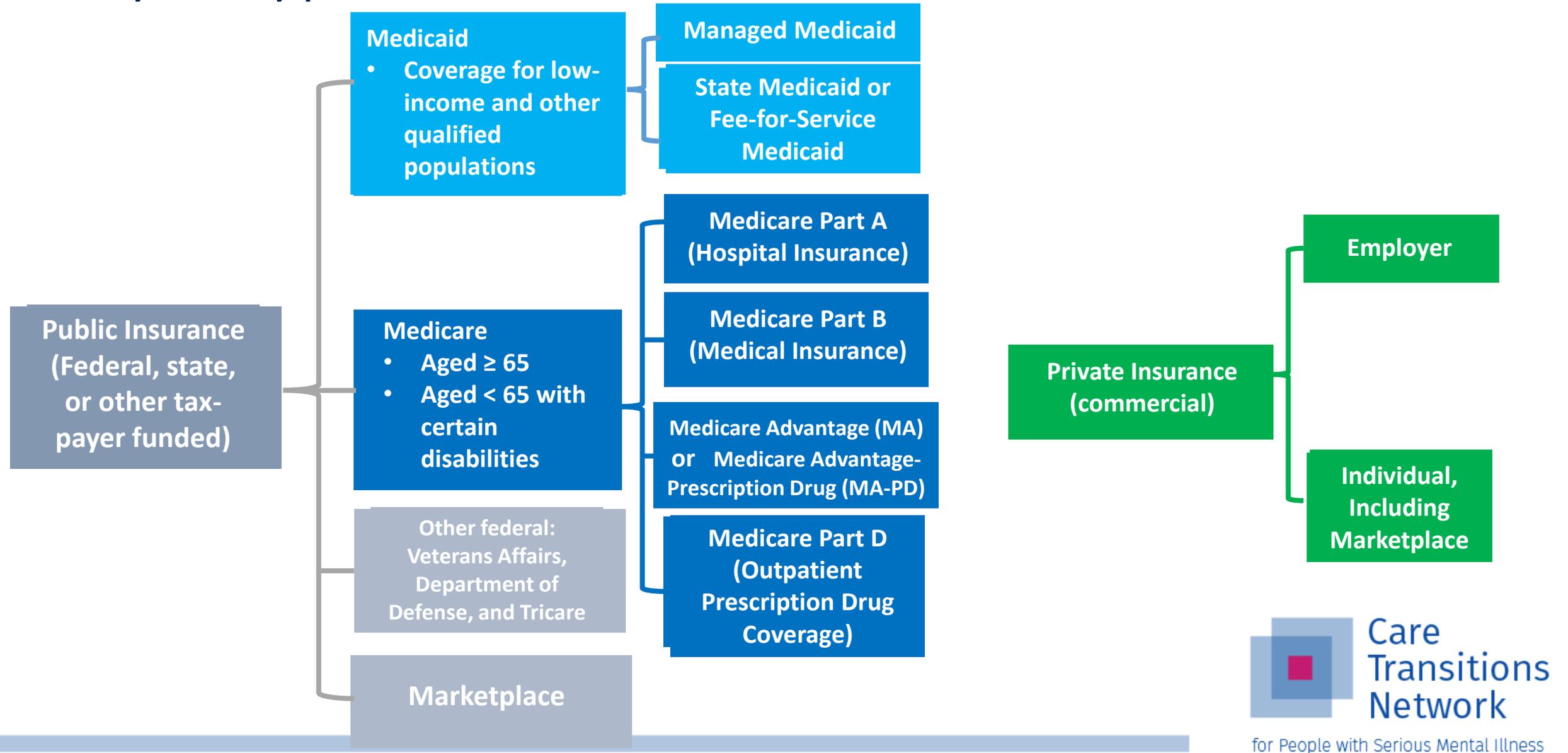
Payer Type

- Obtaining coverage for LAIs will change with value-based payment.
- Until then, coverage will vary based on the type of insurance and each payer's specific policies regarding coverage and reimbursement.
- There are 2 major types of payers that provide coverage for those with schizophrenia:
 - **Medicaid and Medicare:** public insurance funded by government
 - **Private insurance:** includes plans through the health insurance marketplace

Payer Type

- **Medicare** provides coverage to qualified elderly and disabled individuals.
- **Medicaid** is an important payer as a primary or secondary source of coverage for various groups such as the disabled, children, pregnant women, and those with little income.
- **Private Payers** may cover LAIs and the medical services associated with their administration.
- Some patients have **overlapping coverage** from different payers, or **gaps in coverage** from one payer that are met by another.

Payer Type



Medicaid

- Medicaid is the largest source of coverage for many people with schizophrenia.
- It covers people with disabilities and people with little income.
- **More than 50% of Medicaid patients** may receive coverage through a Managed Medicaid plan that is administered by a commercial payer.
- Patients enrolled in **Managed Medicaid** plans may have different coverage than patients covered under a **Fee-for-Service Medicaid** program.
- It is important to verify which entity determines prescription drug coverage for LAIs and benefit coverage for each individual patient.

Recent New York State Medicaid Changes

- Behavioral health benefits for adults were paid as **Fee-For-Service (FFS)**
- Since July 2016, most are now “carved in” to **Medicaid Managed Care (MMC)**.
- MMC plans began covering atypical injectables for **Supplemental Security Income (SSI)** enrollees and SSI-related enrollees. These were previously covered under Fee-For-Service.
- MMC plans will cover **typical and atypical long-acting injectables** as both a **pharmacy and medical benefit**.
- Prior authorization for typical long-acting antipsychotics will not be required.
- **These changes have improved access to LAIs for Medicaid recipients.**

Medicaid Coverage for Atypical LAIs

Member Qualified for SSI or is SSI Related	Member geographic Location	Age	Coverage Provided By	Available through the Medical Benefit	Available through the Pharmacy Benefit
No	Entire State	All Ages	MMC Plan (effective 10/1/11)	Yes	Yes
Yes	New York City	21 or older	MMC Plan (effective 10/1/15)	Yes	Yes
Yes	Entire State	20 or younger	Medicaid FFS	Yes	No*
Yes	Outside of New York City	21 or older	MMC Plan (effective 7/1/16)	Yes	Yes

*The New York State Department of Health is working on implementing system changes to allow for atypical long-acting injectables, as well as injectable naltrexone extended release (Vivitrol) to be covered as a pharmacy benefit for those enrollees in MMC who continue to access these medications through Medicaid FFS (as shown above).

June 2016 New York State Medicaid Update



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NY Managed Medicaid plan coverage of LAIs

- Until the migration toward Managed Medicaid, states purchased healthcare services for Medicaid beneficiaries largely on a fee for service basis.
- Under **Medicaid Fee-for-Service plans**, providers are paid for services based on a set fee schedule, usually a fixed percentage of the Medicare rate or tiered based on the patients' income.
- Under various **Managed Medicaid plans**, coverage and reimbursement are variable based on the specific plan.

NY Managed Medicaid plan coverage of LAIs

- The New York State Medicaid Managed Care Pharmacy Benefit Information Center
- <http://mmcdruginformation.nysdoh.suny.edu/>
- Use “drug look up search” to look up formulary drugs
- Choose tab “mental health quicklist”
- Select “Injectable Antipsychotics”, select “All plans” and click “begin look up”
- Click on the "C" to find out if a covered drug has
 - limited strengths on formulary
 - required step therapy
 - quantity limits
 - prior authorization requirements

Drug Name	Form	AC	AHP	CDPHP	CR	EBCBSHP	EX	FC	HF	HIPEH	HNBCBS	IHP	MPHP	MVP	TC	UHC	VNSNY	WHP	YC
<i>Injectable Antipsychotics</i>																			
ABILIFY MAINTENA	INJECTION	C	C	C	C	NC	NC	C	C	C	NC	NC	C	C	C	C	C	C	C
ARISTADA	SYRINGE	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	C	C	C	NC	NC	NC	C
<i>fluphenazine</i>																			
<i>decanoate</i>	INJECTION	C	C	C	C	C	NC	C	C	NC	C	NC	C	C	C	C	C	C	C
GEODON	INJECTION	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	C	NC	NC	C	NC	NC
HALDOL																			
DECANOATE	INJECTION	NC	NC	C	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
<i>haloperidol</i>																			
<i>decanoate</i>	INJECTION	C	C	C	C	C	C	C	C	NC	C	NC	C	C	C	C	C	C	C
INVEGA SUSTENNA	SYRINGE	C	C	C	C	NC	NC	C	C	NC	NC	NC	C	C	C	C	C	C	C
INVEGA TRINZA	SYRINGE	C	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	C	C	NC	C	NC	NC	C
RISPERDAL																			
CONSTA	SYRINGE	C	C	C	C	C	NC	C	C	C	NC	NC	C	C	C	C	C	C	NC
ZYPREXA RELPREVV	INJECTION	C	C	C	C	C	NC	C	NC	NC	NC	NC	NC	C	C	NC	C	NC	C

UPPERCASE indicates brand name drug, lowercase indicates generic name drug, C=Covered, NC=Not Covered

Medicare

- Treatment of schizophrenia can involve multiple sites of care over time.
- **Medicare Part A** covers LAIs administered while inpatient under bundled payment with other inpatient services.
- **Medicare Part B** covers outpatient mental healthcare. It may cover physician administered drugs such as LAIs if drugs are not already covered under a commercial plan or Medicaid, or if the patient does not have Medicaid Part D.
- **Medicare Advantage** is managed Medicare combining Parts A and B including prescription drug coverage **Medicare Advantage Prescription Drug (MA-PD)** plans. LAIs are usually not covered this way.



Medicare Part D

- **Medicare Part D** is an optional managed benefit which covers outpatient prescription drugs.
 - For patients with low income they may automatically qualify via **Dual Medicaid/Medicare enrollment** or as a **Low Income Subsidy beneficiary**.
 - Medicare Part D is usually how outpatient LAIs are covered.
 - Part D benefits are administered by private insurance plans that contract with CMS.
- *Coverage and reimbursement with **Medicare Part D** vary based on the plan.

Medicare Part D

- There is an **initial deductible** that must be met, thereafter
 - **Initial Coverage Phase** – covers 75% before the 2016 standard limit of \$3,310 of retail cost is met, then
 - **Secondary Coverage** - covers 55% of brand cost and 42% of generic cost, then
 - **Catastrophic Coverage Phase** – once out of pocket drug costs exceed \$4,850, covers about 95% of retail price.
- *This essentially means coverage and reimbursement are also **variable throughout the year based on the amount of coverage used.**

Obtaining the LAI

- Several options exist for obtaining LAIs depending on preferences and payer requirements.
 - Order LAI and submit claim (**buy and bill**)
 - **Specialty Pharmacy**
 - Retail Pharmacy (in certain circumstances)
- It is important to always check with each of the patients' payers prior to ordering or administering the LAI to verify the policies for a given patient's insurance.

Benefit Category

- There are 2 benefit structures commonly used to cover costs of LAIs:
- **Medical Benefit**
- **Pharmacy Benefit**

The benefit category determines whether the LAI is obtained via the “**buy-and-bill**” process or via a **specialty pharmacy**.

When an LAI is covered as a pharmacy benefit

- The prescription is submitted to the pharmacy (specialty, retail, or mail order).
- The pharmacy ships the medication to the site of service.
- In some cases, the payer may specify that the prescription be filled by a **specialty pharmacy**.
- In these cases, the pharmacy is responsible for submitting the claim for the LAI.
- The healthcare professional bills for administering the injection and any other professional services.

When the LAI is covered as a medical benefit

- Providers and CMHCs may be able to purchase and administer the LAI in the office-setting.
- This process, known as “**buy-and-bill**” allows the healthcare professional to use their NPI number to bill for different components of treatment.
- These include cost of purchasing the medication, the injection/administration, and any other services (such as E&M service).

Site of Service

- The site of service can influence which benefit category covers the LAI.
- If site of service is an outpatient location such as the **physicians office** or **CMHC**
 - Benefit category can be medical or pharmacy
 - *Roughly 80% of the time*, LAIs will be covered as a **pharmacy benefit**.
- If site of service is a **partial hospitalization** program
 - Usually coverage category is **medical benefit**
- Contacting the payer directly as part of an insurance benefit verification is the best way to determine benefit structure and coverage.

Benefit Verification Checklist

When calling a payer to verify benefits, the following key questions should be considered:

Benefit Verification Questions

- Is the LAI covered as a medical or pharmacy benefit or both?
- Are there any special distribution requirements?
- Does the patient have other insurance benefits that will need to be coordinated?
- Is prior authorization required?
- What is the prior authorization process?
- What is the phone number or fax number for the authorization department?
- How long will it take?
- What information is required?

Benefit Verification Checklist

Patient Cost Questions

- What is the patient's deductible?
- Has the deductible been met? If not what amount has been applied to date?
- What is the patient's co-payment or co-insurance for the drug?
- Does the patient have an out-of-pocket maximum?
- Has the out of pocket maximum been met? If not, what amount has been applied to date?
- Does the patient have an annual or lifetime benefit maximum?
- Has the benefit maximum been met? If not, what amount has been applied to date?

Benefit Verification Checklist

Reimbursement Questions

- What are the coding and claim submission requirements?
- What is the reimbursement amount for the LAI in question based on the patient's plan?
- What is the reimbursement amount for the administration procedure?
- What is the process for submitting for reimbursement?

Suggestions for Monitoring Benefit Changes

- Keep a spreadsheet of patients receiving LAIs to include:
 - specific medication
 - insurance company
 - whether coverage is a pharmacy or medical benefit
 - contact number
 - coverage determination
 - duration of coverage/when next authorization is required
- Ask patients at every injection visit whether their insurance has changed.

Functions that Need to be Staffed

- Patient-specific benefit verification
- Stocking relevant equipment (medications, disposables...)
- Prescription of the LAI
- Administration of the LAI
 - Physician, Physician Assistant, NP, RN, or LPN can fill this role
 - The most cost effective option would be the LPN

Reimbursement Forms

- Forms used for reimbursement for LAIs for Medicare beneficiaries are also used by some Medicaid programs and some private insurances.
- Private payers can provide information about their specific submissions forms and processes.
- **Claim Form CMS-1500**
 - Used for services provided to Medicare beneficiaries in a physician's office.
- **Claim Form CMS-1450 (UB-04)**
 - Used for services provided in hospitals, skilled nursing facilities, hospice, and other institutions.

Coding Specific to LAI Reimbursement

- Healthcare Common Procedure Coding System (HCPCS)
 - A set of health care procedure codes.
 - Based on the American Medical Association's **Current Procedural Terminology** (CPT).
 - Medicare requires their use to report physician-administered drugs.
 - The type of code will depend on the site of service.
 - Drugs administered by injection will have a 5-digit code starting with "J".
- National Drug Code (NDC)
 - Usually reserved for billing by pharmacies
 - Some private payers and the majority of Medicaid fee-for service programs require NDC for billing
 - FDA uses a 10-digit code (5-3-2 format), payers often require an 11-digit code (5-4-2) format for claims and billing.

HCPCS and National Drug Codes

HCPCS	Generic/Trade	Approximate Retail Price	NDC
J1631	haloperidol decanoate	50 mg/mL (1 vial, 1 mL): \$105.18 100 mg/mL (1 vial, 1 mL): \$191.25	Varies by manufacturer
J2680	*fluphenazine decanoate	25 mg/mL (1 vial, 5 mL): \$165.64	Varies by manufacturer
J2794	risperidone microspheres Risperdal Consta	12.5 mg (1 syringe, 2 mL): \$220.87 25 mg (1 syringe, 2 mL): \$439.20 37.5 mg (1 syringe, 2 mL): \$657.58 50mg (1 syringe, 2 mL): \$875.95	50458-0309-11 50458-0306-11 50458-0307-11 50458-0308-11
J2426	paliperidone palmitate Invega Sustenna	39 mg (1 syringe, 0.25 mL): \$421.90 78 mg (1 syringe, 0.5 mL): \$815.80 117 mg (1 syringe, 0.75 mL): \$1215.68 156 mg (1 syringe, 1 mL): \$1622.65 234 mg (1 syringe, 1.5 mL): \$2518.88	50458-0560-01 50458-0561-01 50458-0562-01 50458-0563-01 50458-0564-01

*Prices of LAIs vary by pharmacy.

www.goodrx.com ; *www.blinkhealth.com; www.epocrates.com



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HCPCS and National Drug Codes

HCPCS	Generic	Approximate Retail Price	NDC
J2426	paliperidone palmitate Invega Trinza	273 mg (1 syringe, 0.875mL): \$2,333 410 mg (1 syringe, 1.315mL): \$3,496.58 546 mg (1 syringe, 1.75mL): \$4,660.27 819 mg (1 syringe, 2.625mL): \$6,987.25	50458-0606-01 50458-0607-01 50458-0608-01 50458-0609
J2358	olanzapine pamoate Zyprexa Relprevv	210 mg per vial (1 vial): \$656.70 300 mg per vial (1 vial): \$2029.01 405 mg per vial (1 vial): \$1372.69	0002-07635-11 0002-07636-11 0002-07637-11
J0401	aripiprazole monohydrate Abilify Maintena	300 mg per vial (1 vial): \$1491.62 400mg per vial (1 vial): \$1985.50	59148-0018-71 59148-0019-71
J0401	aripiprazole lauroxil Abilify Aristada	441mg (1 syringe, 1.6mL): \$1,198.20 662mg (1 syringe, 2.4mL): \$1,795.50 883mg (1 syringe, 3.2mL): \$2,367.55	65757-0401-03 65757-0402-03 65757-0403-03

www.goodrx.com ; *www.blinkhealth.com; www.epocrates.com



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Coding Specific to LAI Reimbursement

- Current Procedural Terminology (CPT)
 - 96372, Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular
- Evaluation and Management Services
 - If the provider administering the LAI also performs a follow up visit on the same day of injection, **they can bill for an E&M code in addition** to billing for the injection procedure.
 - Add **Modifier “.25”** to the end of the E&M service code
 - *“Significant, separately identifiable evaluation an management service by the same physician on the same day of the procedure or other service.”*

Coding Specific to LAI Reimbursement

- Revenue Code
 - Revenue codes categorize hospital services by revenue center to report cost data.
 - 0250 – General classification, Pharmacy
 - 0510 – Clinic
 - 0636 – Drugs requiring detailed coding
- Place of Service (POS) Codes
 - POS 11, Office
 - POS 22, Outpatient hospital
 - POS 52, Psychiatric facility-Partial Hospitalization
 - POS 53, Community Mental Health Center

Steps to implementing LAI treatment service

- 1) Education
- 2) Implementation
- 3) Evaluation

Achieving operational efficiencies

Realities of LAI Treatment Service

- Requires minimal staffing to implement.
- Is efficient, particularly in context of an adherence clinic.
- The use of LAIs represents high quality evidence-based care.

Education

- Educate clinicians, service planners, and managers with the background clinical science related to relapse prevention and its relationships to outcomes and recovery.
- As part of the Care Transitions Network, high quality education is available via the CTN Consultation service.

Education

- Use education to pre-emptively counter resistance to change
- Concerns workload will increase
- Ensure key roles of clinicians won't be usurped
- Address knowledge gaps between medical and psychosocial treatments
- Present evidence for LAIs as a relapse prevention strategy
- LAIs will support, not hinder, advocacy for patients' wellbeing

Haddad P, Lambert T, Lauriello J. 2016.

Lambert TJ, Kane J, Kissling W, Paralleda E (2010).



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Attention to Language

- “Depot” may have negative connotations.
- May be stigmatized as a modality only for “noncompliant patients”.
- “Long Acting Formulation” or “Long Acting Injectable” is a preferable substitute.
- “Compliance” may have problematic, non-patient centered connotations.
- “Adherence” is a preferable substitute.
- Consider names with positive connotations such as “Recovery clinic”
- Adherence is an issue common to all patients, not only those burdened by serious mental illness.
- LAIs should be an option considered for and discussed with all patients on oral antipsychotics.

Treatment Goals

- Facilitate early detection of warning signs of relapse and quick crisis response
- Follow up on those who no show for appointments
 - Assume this behavior is a warning sign of relapse
- Appointment focus is broader than positive symptoms
 - Use service utilization measures to track outcomes
- Shared decision making
- Flexibility with appointments based on patient need

Haddad P, Lambert T, Lauriello J. 2016.

Lambert TJ, Kane J, Kissling W, Paralleda E (2010).



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Psychosocial Recovery Program

- While antipsychotic medication is the “cornerstone” of management, for many patients pharmacotherapy alone is not enough to enable recovery.
- Layering psychosocial treatments may allow a greater degree of recovery.
- Topics should be meaningful and effective and allow active participation.

Typical Topics Covered by Psychosocial Programs

- Recovery Strategies
- Practical facts on mental illness
- Stress-vulnerability model
- Coping mechanisms
- Treatment strategies
- Building social support

Typical Topics Covered by Psychosocial Programs

- Using medication effectively
- Drug and alcohol use
- Reducing relapses
- Coping with problems and persistent symptoms
- Getting your needs met in the mental health system
- Healthy lifestyles

Implementation

Schedule Considerations

- How frequently will the clinic be held?
- How many hours per day will the clinic be open?
- What is the best day for the clinic?

Implementation

Space Considerations

- Where will patients wait on arrival?
- What rooms can be used?
- Is there access to a refrigerator for medication storage and blood samples?

Implementation

Staffing Considerations

- Will patients need transport to or from the clinic? How will this be provided?
- What current staff can be used for the clinic?
- Who will give the injections?
- Who will maintain the appointment book? How will entries be recorded in the patients' medical records?

Implementation

- Identify existing human resources
- Identify a suitable location
- Provide adequate space for groups and individual therapy
- Provide adequate space for medical examination and injections
- Assess training needs and consult Practice Transformation Network
- Establish clear and streamlined referral, evaluation, and treatment process
- Ensure documentation is completed and appropriately filed in a timely manner

Evaluation

- Some clinics may find it helpful to formally track some **outcome measures** that are easily monitored.
- **Service utilization** outcomes are the most important and some (such as missed appointments) may already be tracked in many clinics.
- Consultants from the **Practice Transformation Network** can assist with education about more advanced optional measures including quality of life, functional improvements, and psychopathology.

Evaluation

- A LAI service should save costs by decreasing emergency health care utilization.
- Tracking these outcomes can justify the service and provide data to guide adjustments based on the particular needs of the population.
- Service utilization measures
 - **Yearly hospital admission number** and **hospitalization days** should be expected to decrease.
 - **Contacts with case management** and **acute service contacts** (after hours phone calls, mobile crisis utilization, emergency department visits) represent decompensation and may decrease due to more consistent antipsychotic blood level.
 - **Missed appointments** represent loss of revenue and may be an indirect measure of decompensation.

Success factors for adherence clinics

- Finding the right staff to meet the clinic's needs.
- Effective communication and trust between the team and other staff involved in patients' care.
- Clear criteria that allow clinicians to identify appropriate patient referrals.

Moors A, French C, Absalan F, Lambert T. 2011

Success factors for adherence clinics

- Appropriate physical space to house the clinic.
- Flexibility to meet the unique needs of the patients.
- Open-mindedness of administrators/managers and an open-minded culture towards initiating the service.

Moors A, French C, Absalan F, Lambert T. 2011

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Thank you!

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