Developing Your Antipsychotic Injectable Service

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Objectives

- Review available long-acting injectable anti-psychotic medications.
- Compare and contrast available opportunities to administer longacting injectable anti-psychotics.
- Discuss business components of a long-acting injectable antipsychotic service including inventory management, appointment scheduling, marketing, and payment structures.
- Illustrate challenges and tips/tricks with implementing a longacting injectable anti-psychotic service.

Socrative info

- Please visit m.socrative.com for polling or Socrative App
- Room is MELODY926

Background

- Schizophrenia affects 1.1% of adults in US
- Bipolar affects 1% of adults in US
- Nonadherence is associated with increased relapse rates, increased hospitalization rates, hostility, higher costs of care, and greater mortality and morbidity
 - 40-60% in schizophrenia
 - 10-60% in bipolar
- Long-acting injectable antipsycotics (LAIAs) aim to improve medication adherence

Clinical Evidence of LAIs

- Similar efficacy and safety between LAIAs
- Decreased relapse rates compared to placebo
- Inconsistent data in studies comparing LAIAs to oral antipsychotics
 - Study design
- LAIAs in bipolar disorder limited to risperidone and aripiprazole

Currently Available LAIAs

	Risperdal Consta® (risperidone)	Zyprexa Relprevv® (olanzapine pamoate)	Invega Sustenna® (paliperidone palmiate)	Invega Trinza® (paliperidone palmiate)	Abilify Maintena® (aripiprazole monohydrate)	Aristada® (aripiprazole lauroxil)
Manufacturer	Janssen	Lilly	Janssen	Janssen	Otsuka	Otsuka
Date approved	2003	2009	2009	2015	2013	2015
Indications	Schizophrenia and bipolar disorder	Schizophrenia	Schizophrenia	Schizophrenia	Schizophrenia and bipolar disorder	Schizophrenia
Administration location	IM (deltoid or gluteal)	IM (gluteal only)	IM (deltoid or gluteal)	IM (deltoid or gluteal)	IM (deltoid or gluteal)	IM (deltoid or gluteal)
Administration frequency	Q2 weeks	Q2-4 weeks	Q4 weeks	Q4 weeks	Q4 weeks	Q4-6 weeks
Loading dose	No	Yes	Yes	No	No	No
Oral supplementation	Yes- 3 weeks	No	no	no	Yes- 2 weeks	Yes- 3 weeks
Storage	35-45° F	Room temp	Room temp	Room temp	Room temp	Room temp

Adverse Drug Events

Injection site reaction, weight gain, fatigue, headache, suicide

Risperidone

Paliperidone

Aripiprazole

Parkinsonism, dizziness, akathisia, constipation, dyspepsia, pain in extremity, dry mouth

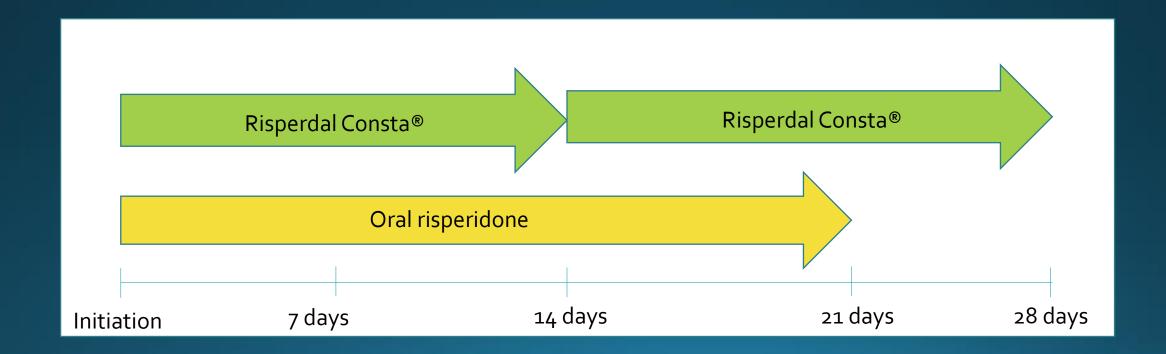
Dizziness, akathisia, extrapyramidal disorder

Akathisia

Black Box Warning: Increased mortality in elderly patients with dementia- related psychosis.

Risperdal Consta® Dosing

- 25 mg IM every 2 weeks
 - Can increase to 37.5 mg or 50 mg (maximum dose)



Dose Adjustments

- Renal or hepatic impairment- can use 25mg or 12.5mg Q2 weeks
- CYP 3A4 inducers
- CYP 2D6 inhibitors

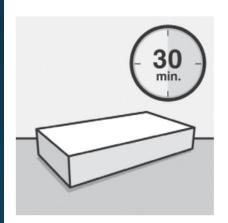
Risperdal Consta® Missed Doses

No data- refer to provider

Step 1

Assemble components

Take out dose pack



Wait 30 minutes

Remove dose pack from the refrigerator and allow to sit at room temperature for at least **30 minutes** before reconstituting.

Do not warm any other way.

Connect vial adapter to vial

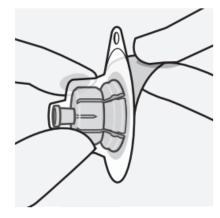


Remove cap from vial

Flip off colored cap from vial.

Wipe top of the grey stopper with an <u>alcohol swab</u>. Allow to air dry.

Do not remove grey rubber stopper.



Prepare vial adapter

Hold sterile blister as shown. Peel back and remove paper backing.

Do not remove vial adapter from blister.

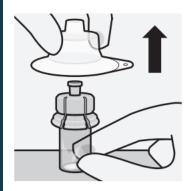
Do not touch spike tip at any time. This will result in contamination.



Connect vial adapter to vial

Place vial on a hard surface and hold by the base. Center vial adapter over the grey rubber stopper. Push vial adapter straight down onto vial top until it snaps securely into place.

Connect prefilled syringe to vial adapter



Remove sterile blister

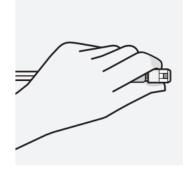


Remove vial adapter from sterile blister only when you are ready to remove the white cap from the prefilled syringe.

Keep vial vertical to prevent leakage. Hold base of vial and pull up on the sterile blister to remove.

Do not shake.

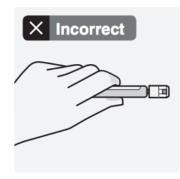
Do not touch exposed luer opening on vial adapter. This will result in contamination.

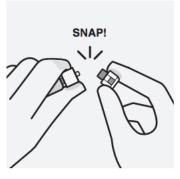


Use proper grip

Hold by white collar at the tip of the syringe.

Do not hold syringe by the glass barrel during assembly.



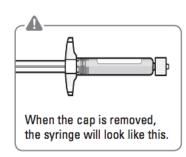


Remove cap

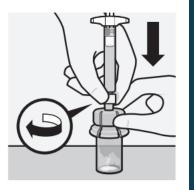
Holding the white collar, snap off the white cap.

Do not twist or cut off the white cap.

Do not touch syringe tip. This will result in contamination.



The broken-off cap can be discarded.



Connect syringe to vial adapter

Hold vial adapter by skirt to keep stationary.

Hold syringe by white collar then insert tip into the luer opening of the vial adapter.

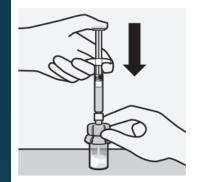
Do not hold the glass syringe barrel. This may cause the white collar to loosen or detach.

Attach the syringe to the vial adapter with a firm <u>clockwise</u> <u>twisting motion</u> until it feels snug.

Do not over-tighten. Over-tightening may cause the syringe tip to break.

Step 2

Reconstitute microspheres



Inject diluent

Inject entire amount of diluent from syringe into the vial.



Vial contents will now be under pressure.

Keep holding the plunger rod down with thumb.

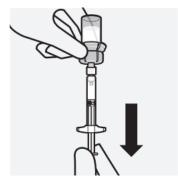


Suspend microspheres in diluent

Continuing to hold down the plunger rod, **shake vigorously for at least 10 seconds**, as shown.

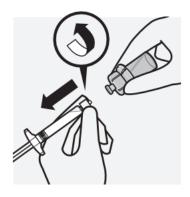
Check the suspension.
When properly mixed, the suspension appears uniform, thick and milky in color.
Microspheres will be visible in the liquid.

Immediately proceed to the next step so suspension does not settle.



Transfer suspension to syringe

Invert vial completely. Slowly pull plunger rod down to withdraw entire contents from the vial into the syringe.



Remove vial adapter

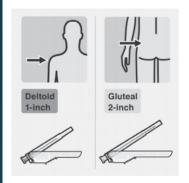
Hold white collar on the syringe and unscrew from vial adapter.

Tear section of the vial label at the perforation. Apply detached label to the syringe for identification purposes.

Discard both vial and vial adapter appropriately.

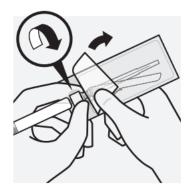
Step 3

Attach needle



Select appropriate needle

Choose needle based on injection location (gluteal or deltoid).



Attach needle

Peel blister pouch open part way and use to grasp the base of the needle, as shown.

Holding the white collar on the syringe, attach syringe to needle luer connection with a firm clockwise twisting motion until snug.

Do not touch needle luer opening. This will result in contamination.



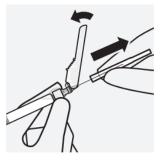
Resuspend microspheres

Fully remove the blister pouch.

Just before injection, shake syringe vigorously again, as some settling will have occurred.

Step 4

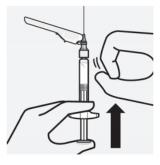
Inject dose



Remove transparent needle protector

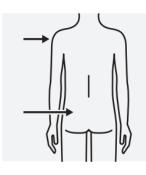
Move the needle safety device back towards the syringe, as shown. Then hold white collar on syringe and carefully pull the transparent needle protector straight off.

Do not twist transparent needle protector, as the luer connection may loosen.



Remove air bubbles

Hold needle upright and tap gently to make any air bubbles rise to the top. Slowly and carefully press plunger rod upward to remove air.

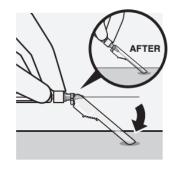


Inject

Immediately inject entire contents of syringe intramuscularly (IM) into the gluteal or deltoid muscle of the patient.

Gluteal injection should be made into the upper-outer quadrant of the gluteal area.

Do not administer intravenously.



Secure needle in safety device

Using one hand, place needle safety device at a 45-degree angle on a hard, flat surface. Press down with a firm, quick motion until needle is fully engaged in safety device.

Avoid needle stick injury:

Do not use two hands.

Do not intentionally disengage or mishandle the needle safety device.

Do not attempt to straighten the needle or engage the safety device if the needle is bent or damaged.



Properly dispose of needles

Check to confirm needle safety device is fully engaged. Discard in an approved sharps container.

Also discard the unused needle provided in the dose pack.

Invega Dosing

Invega Sustenna® Day 1: 243mg

Day 8: 156mg

Day 36: Maintenance dose

Invega Trinza® (after 4 months of Invega Sustenna®)

If the last dose of Invega Sustenna® was:	Initiate Invega Trinza® at the following dose:
78 mg	273 mg
117 mg	410 mg
156 mg	546mg
234 mg	819 mg

Invega Dose Adjustments

- Renal impairment
 - Mild (CrCl 50-80 ml/min)
 - Initiate with a dose of 156 mg on treatment day 1 and 117 mg one week later
 - 78 mg Q4 weeks
 - Moderate to severe (CrCl <50 ml/min)
 - Do not use
- Avoid coadministration with Strong CYP3A4/P-glycoprotein Inducers

Invega Sustenna® Missed Initiation Doses

< 4 weeks

- Administer the second initiation dose as soon as possible.
- It is recommended to administer a third injection of (maintenance dose) 5 weeks after the first injection (regardless of the timing of the second injection).
- Resume regular monthly dosing in either the deltoid or gluteal muscle.

4-7 weeks

- Administer a deltoid injection as soon as possible.
- •Administer a second deltoid injection 1 week later.
- •Resume regular monthly dosing in either the deltoid or gluteal muscle.

>7 weeks

• Restart dosing with recommended initiation plan.

Invega Sustenna® Missed Maintenance Doses

4-6 weeks Resume regular monthly dosing as soon as possible at patient's previously stabilized dose, followed by injections at monthly intervals.

>6 weeks-

- Continue dosing at patient's previously stabilized dose.*
- Administer a deltoid injection as soon as possible.
- Administer a second deltoid injection 1 week later at same dose.
- Resume administering previously stabilized dose in the deltoid or gluteal muscle 1 month after the second injection.

>6 months

• Restart dosing with recommended initiation plan.

Invega Trinza® Missed Maintenance Doses

Early or late by 2 weeks

 Patients may be given the injection ±2 weeks from their scheduled 3-month dose

3.5-4 months

• Previous dose should be administered as soon as possible, then continue with 3-month injections

4-9 months

• Reinitiation regimen

> 9 months

• Reintiate Invega Sustenna®. Resume Invega Trinza® after 4 months

Invega Trinza® Reinitiation Regimen

If the last Invega Trinza® dose was:	Administe Sustenna® week a	2 doses, 1	Then administer Invega Trinza®
	Day 1	Day 8	
273 mg	78 mg	78 mg	273 mg
410 mg	117 mg	117 mg	410 mg
546mg	156 mg	156 mg	546mg
819 mg	156 mg	156 mg	819 mg

1 Select needle¹

Needle selection is determined by injection area and patient weight.

If administering a **deltoid** injection



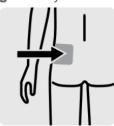
If patient weighs: Less than 90 kg pink hub

22G × 1"

90 kg or more yellow hub

22G × 1½"

If administering a **gluteal** injection



If patient weighs: Less than 90 kg yellow hub

22G × 1½"

90 kg or more yellow hub

22G × 1½"

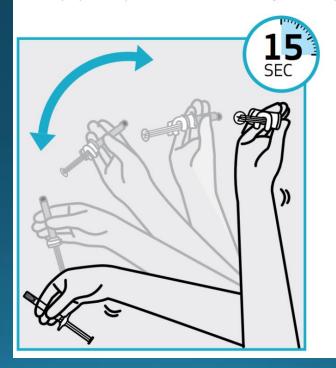
Immediately discard the unused needle in an approved Sharps Container. Do not save for future use.

2 Prepare for injection

SHAKE VIGOROUSLY for at least 15 seconds

With the syringe tip pointing up, SHAKE VIGOROUSLY with a loose wrist for at least 15 seconds to ensure a homogeneous suspension.

NOTE: This medication requires longer and more vigorous shaking than the 1-month paliperidone palmitate extended-release injectable suspension.



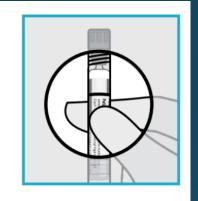
10 seconds for Invega Sustenna®

Check suspension

After shaking the syringe for at least 15 seconds, check the liquid in the viewing window.

The suspension should appear uniform and milky white in color.

It is also normal to see small air bubbles.



Grasp needle pouch

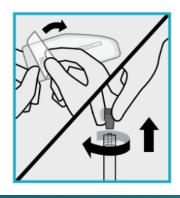
Fold back needle cover and plastic tray. Then, firmly grasp the needle sheath through the pouch, as shown.



Open needle pouch and remove cap

First, open needle pouch by peeling the cover back halfway. Place on a clean surface.

Then, holding the syringe upright, twist and pull the rubber cap to remove.



Attach needle

With your other hand, hold the syringe by the Luer connection and attach it to the safety needle with a gentle clockwise twisting motion.

Do not remove the pouch until the syringe and needle are securely attached.



Remove needle sheath

Pull the needle sheath away from the needle in a straight motion.

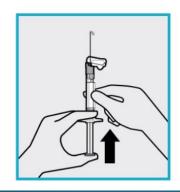
Do not twist the sheath, as this may loosen the needle from the syringe.



Remove air bubbles

Hold the syringe upright and tap gently to make any air bubbles rise to the top.

Remove air by pressing the plunger rod upward carefully until a drop of liquid comes out of the needle tip.

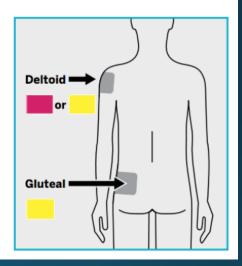


3 Inject¹

Inject dose

Slowly inject the entire contents of the syringe intramuscularly, deep into the selected deltoid or gluteal muscle.

Do not administer by any other route.

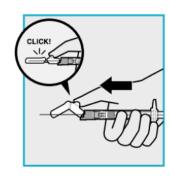


4 After injection¹

Secure needle

After the injection is complete, use your thumb or a flat surface to secure the needle in the safety device.

The needle is secure when a "click" sound is heard.



Dispose properly

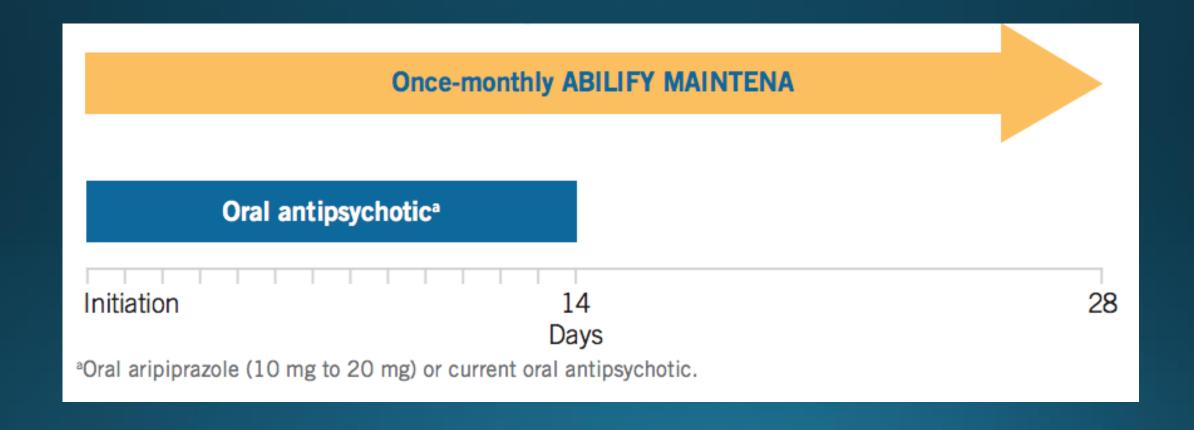
Dispose of the syringe and unused needle in an approved Sharps Container.



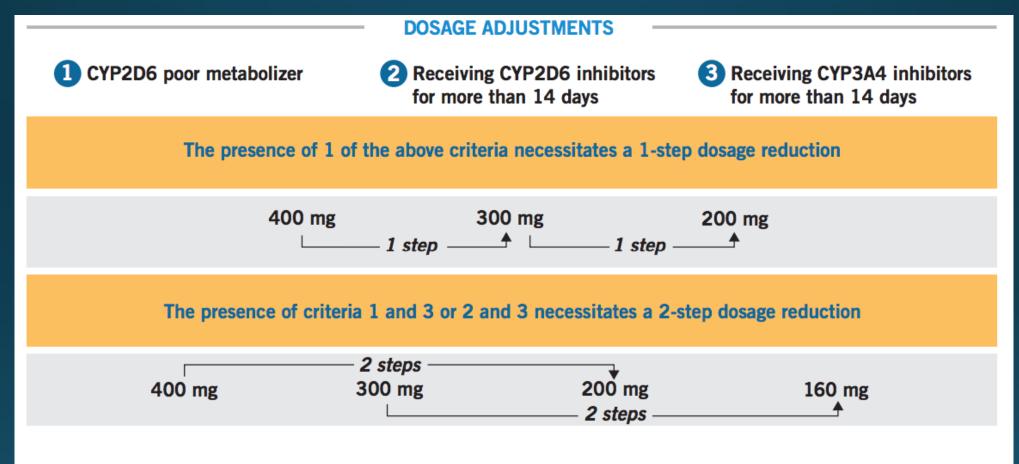


Thin wall safety needles are designed specifically for use with INVEGA TRINZA® (paliperidone palmitate). Unused needle should be discarded and not saved for future use.

Abilify Maintena® Dosing



Abilify Maintena® Dose Adjustments



- ► For patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for more than 14 days
- ▶ Avoid the concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for more than 14 days

Abilify Maintena® Missed Doses

2nd or 3rd doses missed

- 4-5 weeks
 - Administer injection ASAP, followed by injections at monthly intervals.
- >5 weeks
 - Restart concomitant oral aripiprazole for 14 days with the next administered injection.

4th or subsequent doses missed

- 4-6 weeks
 - Administer injection ASAP, followed by injections at monthly intervals
- > 6 weeks
 - Restart concomitant oral aripiprazole for 14 days with the next administered injection.

Abilify Maintena® Administration



Step 1: push plunger rod slightly

Step 2: twist plunger rod until middle

stopper reaches indicator line

Step 3: vertically shake syringe for 20

seconds

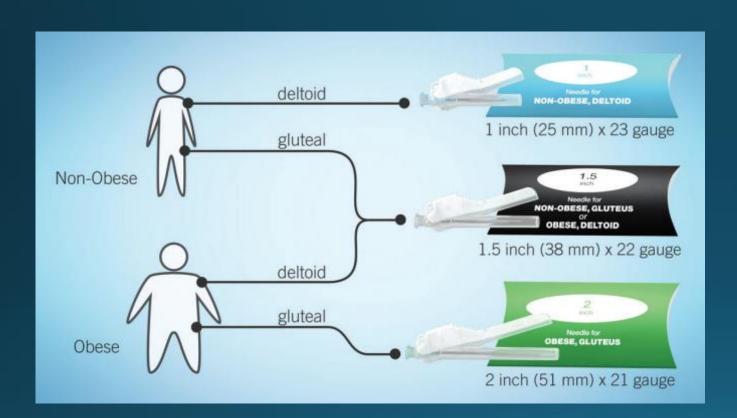
Step 4: inspect syringe (use within

30 min)

Step 5: twist and pull off over cap and

tip cap

Abilify Maintena® Administration



Step 6: choose appropriate needle size

Step 7: expel air in needle

Step 8: slowly inject into deltoid or

gluteal muscle

Step 9: Engage needle safety device

and dispose



Question 1

Which of the following LAIAs is given every 2 weeks?

- a. Risperdal Consta®
- b. Invega Sustenna®
- c. Invega Trinza®
- d. Abilify Maintaina®

Question 2

True or False: Patients must be on Invega Sustenna for 1 year before switching to Invega Trinza®

- a. True
- b. False

Opportunities for LAIA services

	Janssen Connect®	Assure®		
LAIs included Risperdal Consta®, Invega Sustenn Invega Trinza®		Abilify Maintena®		
Enrolling patients	Must be enrolled by Prescriber	Enrolled by Pharmacy or Prescriber		
Marketing	Cannot market to Prescribers	Can market to Prescribers		
Training	Online modules (annual update)	In person training		
Payment structures	Bill for product + administration fee	Bill for product + administration fee Can reimbursed for "storage fee"		

LAIA Service Responsibilities

- Provide private space for injection
- Schedule patient appointments/ make reminder calls
- Make sure prescription (and refills) can be filled
- Counsel the patient
 - Assess treatment efficacy/ adverse drug events
 - Answer questions
- File maintenance
- Inventory management
- Report missed appointments
- Identify drug interactions

Getting Started- Janssen Connect®

Step 1: go to www.Janssenconnect.com



Getting Started- Janssen Connect®

Step 2: Contact Janssen Connect



CONTACT US

Call 1-877-JC-HELP9

Phone: 1-877-524-3579 | Fax: 1-877-785-1124

Monday Through Friday 7:00 am to 7:00 pm CT

For medical inquiries, visit JanssenMD.com

JANSSEN CONNECT® Can Help Bridge the Gaps in Information Along the Treatment Path of Your Patients Living with Schizophrenia

Challenges of Continuity of Care May Lead to Negative Consequences.¹

JANSSEN CONNECT® Was Created to Help Bridge Those Information Gaps.

Janssen Connect® Patient Report Form

JANSSEN CONNECT®

INVEGA SUSTENNA® (paliperidone palmitate)
Patient Injection Report Form

Fax completed form back to ANSSEN CONNECT at 1-877-785-1124 within 24 hours of injection

Patient Information		JANSSEN CONNECT® Patient ID UBC-17-431678-06529									
Name Same							Da	ate of	birth d	_	
Address	i san yadama	-		City		_	State	4		_Zip	
Best contact number			- 1	Best time	to contact		AM		PM		
Alternate patient contact	number	Alternate patient contact number									
njection Administration:						anneces contra	pacementer	overenews.	UNICODER TODOROGIA	-	
njection administered:		Yes, date of injection: Date of next scheduled injection:									
		No, appointment rescheduled in accordance with HCP orders, date:									
27		N	otify HCP if pa	atient canc	els or misses	injectio	n				
Reminder alerts made:		Yes, completed reminder calls to the patient (up to 3 attempts).									
		No, did not complete reminder calls to the patient (up to 3 attempts).									
njection center name: S	unray Drug	store LLC (Clinic)			Sto	re#:	Sun	ray Drugs		
Address 142 South 52nd S						Co	de <u>l</u>	JBC-1	6-06336-	55861	
Administering healthcare profe	essional na	me					Tit	et			
Signature					Date						
Project Andrecta for - By signing this do Screenest with filling.	SCOMMAE YEST O	re elbo condirezo	ç fisahali numcun i	haron bases pen	vided as sueclaed	by stow	Jamesens Rojac	otor Ac	in the control	Perzioes u	ender top adjoining the ex-
Additional Information F	or HCP:										
nitiation dose:		4 mg (1.5 mL)			☐ Day 8: 15				VI 2003 200 100 200 1	_	
HERMANIST STATE OF THE STATE OF	39 mg (0.25	Salara Salara		3 ⁸ 00 - 00 000	117 mg (0.75	5 mL)	D 1	56 mg	(1.0 mL)		234 mg (1.5 ml)
injection site location:	Le	n eltold muscle	☐ Right		3luteal muscle						
AE/PQC REPORTING:											
If a patient reports any alle administer; cancel appoint											ENNA®, do not
f an adverse event or prod	fuct quality	complaint	occurred, re	port ever	t by calling:	1-888	438-648	7. (R	RA#4299) within	n 24 hours.
Do not record any AE/PQC	informati	on on this r	eport.								

Getting Started- Assure®

Step 1: go to www.assurepathways.com/AbilifyMaintena



U.S. FULL PRESCRIBING INFORMATION, including Boxed WARNING, and Medication Guide



PHYSICIAN FINDER

PHARMACY FINDER

LOCAL CARE CENTERS

INSURANCE INFORMATION

ASSURE PATHWAYS FOR ABILIFY MAINTENA® (aripiprazole)

Otsuka America Pharmaceutical, Inc. (OAPI) is committed to enabling patient access to ABILIFY MAINTENA for extended-release injectable suspension.

Step 2: Contact Assure

For assistance, please call the ASSURE Program™ at 855-24-ASSURE (855-242-7787) or contact your ASSURE Program Manager.

Visit <u>www.ASSURE.com</u> for more information.

Assure® Patient Report Form

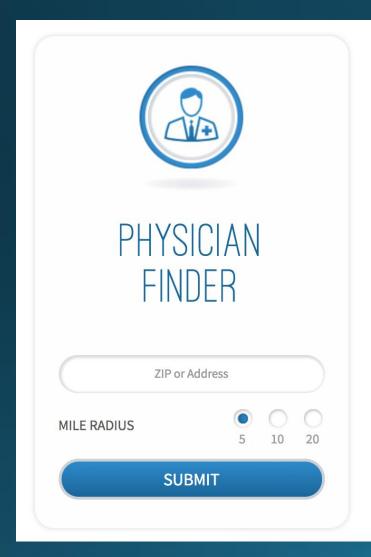
LCC PATIENT **DATA REPORT**

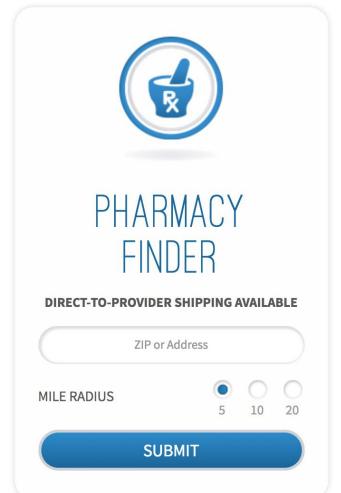
Pharmacy: Please fax within 24 hour

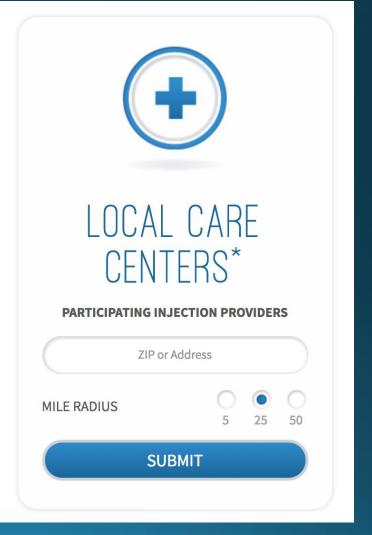
PATIENT AUTHORIZATION (conti	inued)
I understand it is possible for my fauthorization to be subject to re-discistate or federal privacy laws.	PHI disclosed by pharmacy or healthcare provider under this losure by the recipient and no longer protected under applicable
or road and privately family	
Patient Signature	Date Date
Legal Authorized Representative Signature	
Legal Authorized Representative Signature's	Relationship 11/4 14 Date 2 / Date
PATIENT INFORMATION	
Patient Name	DOB P/ Gender: Male Female
(Eirst/Last)	Gender: Li Male & Female
	Email Address Zip Code
Secondary Contact Name	Secondary Contact PH# ()
Insurance Type: Medicare Medicaid	☐ Commercial-Employer ☐ Commercial-State Exchange
	k all applicable): Phone Text Email Secondary Contact
PRESCRIBER INFORMATION	
For data collection purposes only.	Phone Number () 427-1500
Prescriber Name 2, GAN	Phone Number ()
Prescriber Setting: In-Patient Out-Pat	
Prescriber Address	City State Zip Code
INJECTION INFORMATION	
Site Name SUNRAY DYUR Stor	Date of Administration 08 / 10 / 2017
Site Address 142 S 52nd ST	Next Injection Date <u>09</u> / <u>13</u> / <u>2017</u>
City PHILA delphin	Injection Administration: Dosage:
State D4 Zip Code 19139	Deltoid Gluteal 400mg 300mg Other
Site Phone Number (215) 474-46	Drug Acquisition:
Site Fax Number ()	☐ Pharmacy Dispense ☐ Patient Assistance Program Shipment*
	Received Shipment from Payer-Mandated Specialty Pharmacy*
	A received Simplifient from Payer-Mandated Specialty Pharmacy
lave you reviewed all information on this p	age with the patient to ensure it is complete, accurate, and current?
Change(s) from last visit: Yes No	
Please fax this form and (if applicable) your shipp	ing receipt and/or invoice to ASSURE (855-876-2627) if you acquired drug from another

Please see accompanying FULL PRESCRIBING INFORMATION, including BOXED WARNING.

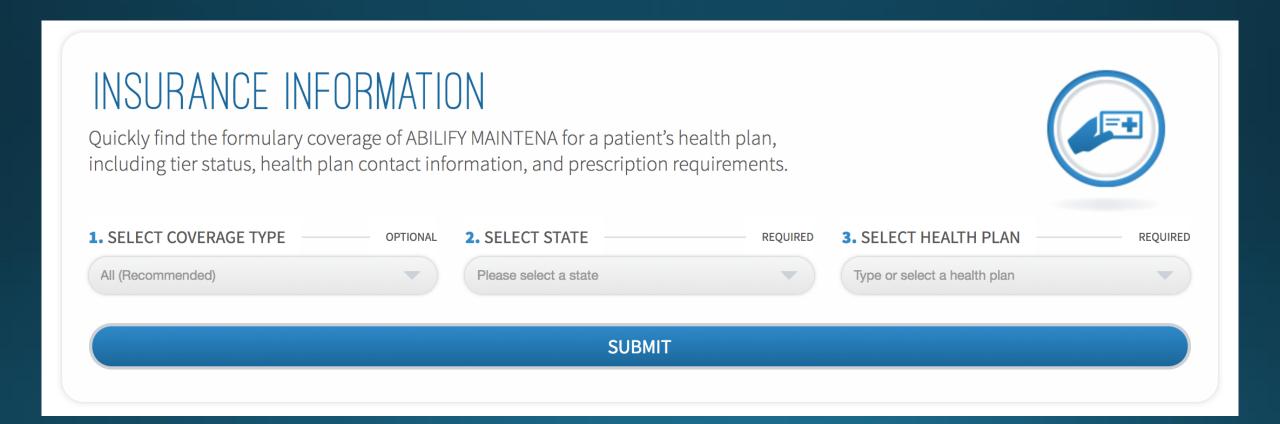
Other Assure Tools







Other Assure Tools



True or False: Pharmacies **CANNOT** enroll patients into the Janssen Connect® program.

- a. True
- b. False

Which of the following is TRUE regarding the Assurance® program

- a. The training is online
- b. You will NOT be reimbursed a storage fee
- c. You are allowed to market your service to physicians
- d. All of the above are true

Which of the following are responsibilities of a LAI service?

- a. Scheduling patient appointments
- b. Counseling the patient at each visit
- c. Reporting missed appointments to provider
- d. All of the above

Challenges- Patient Perceptions

- Patient knowledge/awareness
 - Inaccurate, incomplete, none at all
- Patient Preference
 - Oral vs injectable
 - Daily vs. once weekly or every 2 weeks
- External control
 - Coercive
- Cost
 - Medication and travel to clinic/pharmacy
- Stigma

Challenges- Prescriber

- Limited Knowledge and Experience with LAIAs
- Attitudes and beliefs
- Place of LAIA in guidelines
 - Clear for non-adherence or multiple relapses not first episode or early phases
- Workload
 - Enrolling patients

Challenges/Tips & Tricks-Logistical

Patient No Shows

Use a calendar for appointments, reminder calls

Tie appointment with other vaccinations/ medication pickup

Collect multiple phone numbers

Prescription Adjudication

Run a test claim a few days before appointment

Inventory Management

Use a calendar to decrease time on shelf

Paperwork

Fill out forms completely

Stay up to date on training

Other Tips/Tricks

Build relationships!

- Patients
- Providers

Give out giveaways to patients

Supplies

- Private area
- Sharps
- Band-Aids
- Cotton balls
- Gloves
- Resources on medications you administer

Opportunity for collaborative practice agreements?

Which of the following is a tip/trick for a LAI service?

- a. Having a schedule of appointments/reminders
- b. Running a test claim a few days before patient's appointment
- c. Tying LAI appointment to medication sync pickup date
- d. All of the above

Question 7:

True or False: Evidence shows that patients prefer oral antipsychotics over LAIAs.

- a. True
- b. False

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