APORIA · ISSUE TWO

02

Months Between Pills.

A 47% drop in psychiatric hospitalisation sits in the literature. Indian psychiatrists prescribe long-acting injectables in 9% of acute schizophrenia. The gap is not pharmacology. It is the cost ladder, the cold-chain map, the eight molecules we have and the six we do not.

CLINICAL DILEMMAS IN PSYCHIATRY

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01 / GAP

The nine percent problem

Wei and colleagues followed 70,396 patients with schizophrenia in Hong Kong and compared the same patients during phases on long-acting injectable antipsychotics against phases on oral medication. Psychiatric hospitalisation fell by 47%. Schizophrenia-specific hospitalisation fell by 44%. Suicide attempts fell by 44%. Cardiovascular hospitalisation and extrapyramidal symptoms fell on the LAI phase too. The same year Grover, Sahoo and Mehra surveyed 622 Indian psychiatrists and found that LAIs were prescribed to 9.3% of patients in the acute phase and 18.4% in the stable phase. The Indian Psychiatric Society 2026 schizophrenia guideline now recommends them proactively, not as a last resort. The gap between Wei and Grover is the aporia of this issue.

The pharmacology of LAIs is settled. The dose ranges are in the Maudsley Prescribing Guidelines, now in its 15th edition. The tolerability tradeoffs are mapped. The two-week paliperidone loading schedule, the three-week risperidone oral overlap, the gluteal-only post-injection observation for olanzapine pamoate; all of this is well-rehearsed clinical knowledge. The puzzle is not "should we use LAIs more." The puzzle is which one, when, for which patient, at which cost, in which district.

India has eight LAIs in routine domestic commerce (one of which, aripiprazole monohydrate, is available only by import), and six that the rest of the world prescribes but we do not. The same month a patient pays fifteen hundred rupees a month for paliperidone, the patient in the next chair is paying thirty rupees a month for fluphenazine. The two drugs are not interchangeable. The choice is not pharmacological. It is structural. This issue maps that structure.

> WHAT THIS ISSUE COVERS
>
> Aporia 02 walks the Indian LAI shelf in order of usage frequency, anchors every clinical claim against the Maudsley 15th edition, and surfaces the six formulations the international literature now treats as standard that Indian patients cannot access. The frame is practical. The structure follows the public-sector pillars (four first-generation depots), the private-sector frontier (four second-generation injections), the cost ladder, the oral-overlap matrix, the dose equivalences, the patient-profile decision rules, the bipolar maintenance question, and the Indian decision frame under the Mental Healthcare Act 2017 and the National List of Essential Medicines 2022. The reference list is twelve citations long. Every claim is anchored.

What changed in this literature

The strongest single piece of evidence shifting Indian guideline practice is Wei and colleagues' 2022 self-controlled case series in JAMA Network Open.[1] The within-patient design removes between-patient confounding. The incidence rate ratios match across hospitalisation, suicide-attempt and adverse-event outcomes. The benefit holds across age groups, including patients over sixty, and across subgroups with substance use comorbidity. The 2024 Wang and Leucht meta-analysis of sixty-six randomised trials in acute schizophrenia confirmed the efficacy signal across second-generation LAIs against placebo, with standardised

mean differences between minus 0.62 and minus 0.66.[2] The newer formulations covered in Maudsley 15th (paliperidone six-monthly, aripiprazole two-monthly, risperidone subcutaneous monthly, risperidone ISM) extend the dose-interval frontier from monthly to two-monthly to three-monthly to six-monthly across the SGA class. The Indian formulary has not yet caught up. The six-monthly paliperidone formulation Janssen offered for import was explicitly rejected by the CDSCO Subject Expert Committee in May 2022 on the grounds of "no unmet need."

The Indian shape of the question

Two structural facts of Indian practice carry most of the weight in this entire decision. The first is cost. The cheapest LAI on the Indian shelf, fluphenazine decanoate as Anatensol or generic IP, costs about thirty to fifty rupees a dose, which works out to thirty to eighty rupees a month. The costliest commonly used LAI, paliperidone palmitate as Invega Sustenna, costs about five thousand rupees a dose, or six thousand rupees a month. The Sun Pharma generic, Paliris LA, lands between two and three thousand rupees a month. Risperidone microspheres as Risperdal Consta sit at about eleven thousand rupees a month at the upper end. The same molecule with the same evidence base costs two-hundred-fold more depending on which patient you put it in. The second structural fact is supply. Fluphenazine decanoate is on the National List of Essential Medicines 2022 and is reliably available in government supply chains. None of the other LAIs are. Zuclopenthixol decanoate goes out of stock for months at a time. Aripiprazole monohydrate is available only by import through GNH India. Olanzapine pamoate is technically available but its post-injection delirium and sedation syndrome monitoring requirement is a three-hour observation that most Indian outpatient setups cannot deliver. The frontier of the Indian LAI shelf is not the frontier of Maudsley's. The two move at different speeds.

02 / FIELD

The global field, the Indian shelf

The international LAI literature now covers fourteen molecules. The Indian shelf has nine in routine commerce, of which one (olanzapine pamoate) is import-only and effectively unavailable. The six missing formulations are listed in the right column. The cleanest single distinction is between the public-sector pillars (FGA depots, low cost, government supply, high EPS burden) and the private-sector frontier (SGA injections, urban availability, higher cost, lower EPS burden but variable metabolic and prolactin trade-offs).

IN INDIAN COMMERCE

The nine available

- **Fluphenazine decanoate.** Anatensol, generic IP. NLEM 2022.
- **Haloperidol decanoate.** Movadol LA, Dolteus, generic IP.
- **Flupentixol decanoate.** Fluanxol Depot (Lundbeck), Spenzo Depot (Intas).
- **Zuclopenthixol decanoate.** Clopixol Depot (Lundbeck). Supply patchy.
- **Paliperidone palmitate one-monthly.** Invega Sustenna (J&J), Paliris LA (Sun).
- **Risperidone microspheres.** Risperdal Consta (Janssen).
- **Olanzapine pamoate.** Tolaz LA (Torrent). 210/300/405 mg vials. PDSS observation requirement limits routine outpatient use.
- **Aripiprazole monohydrate.** Abilify Maintena. Import only via GNH India.

NOT IN INDIA

The six absent

- **Paliperidone palmitate three-monthly.** Invega Trinza. No CDSCO marketing authorisation.
- **Paliperidone palmitate six-monthly.** Invega Hafyera / Byannli. CDSCO Subject Expert Committee rejected J&J's import-and-manufacture proposal in May 2022 citing "no unmet need."
- **Aripiprazole lauroxil.** Aristada (Alkermes). United States only.
- **Aripiprazole two-monthly.** Abilify Asimtufii, FDA-approved April 2023. Not in India.
- **Risperidone subcutaneous monthly.** Perseris and Uzedy. United States only.
- **Risperidone ISM, Rykindo.** Newer risperidone formulations. Not in India.

What this issue does with the shelf

The next two chapters walk the Indian shelf in usage order. Public-sector pillars first, because for most Indian patients the FGA depot is the only realistic LAI, and the four FGAs have meaningfully different positions even though their dose ranges and side-effect profiles overlap. Private-sector frontier second, because the cost ladder runs through this group and because Sun Pharma's paliperidone generic has reshaped what an Indian psychiatrist can offer a patient who cannot afford the brand. The six absent formulations get their own chapter, because the gaps in the Indian shelf are themselves a clinical fact (the patient who would benefit most from a three-monthly or six-monthly schedule cannot have one).

> A CLARIFICATION
>
> Three olanzapine injection products coexist on the Indian market and are easily confused. **Oliza Injection** by Intas and **Oleanz Injection** by Sun Pharma are short-acting intramuscular olanzapine at ten-milligram ampoule strength, indicated for acute agitation; these are not depot formulations. **Tolaz LA** by Torrent Pharmaceuticals is the Indian olanzapine pamoate depot, available at 210, 300 and 405 mg per vial (the international Zyprexa Relprevv strengths) and retailed on 1mg, PharmEasy, Practo and GNH India. Tolaz LA is the brand used at most Indian tertiary centres prescribing olanzapine LAI, including the cohorts behind the published Indian PDSS literature.[10] Two distinctions are worth holding: the short-acting Oliza and Oleanz are different molecules in clinical effect from Tolaz LA despite sharing an active ingredient name; and the long-acting Tolaz LA carries the same three-hour post-injection observation requirement as in the international Relprevv label, which constrains routine outpatient use to centres equipped to deliver it.

How to use this issue

The chapters that follow are sequenced from canon to clinic. Chapter 03 lists the twelve Maudsley principles that anchor every clinical decision in the document; read it once and refer back. Chapters 04 and 05 walk the Indian shelf drug by drug, with the public-sector pillars (FGA depots) ahead of the private-sector frontier (SGA injections). Chapter 06 documents what India does not have. Chapter 07 is the cost ladder, the single most decision-shaping factor in Indian practice. Chapter 08 collects the practical initiation, switching and missed-dose tables. Chapter 09 is the patient-profile decision matrix, the nine archetypes that recur in OPD work. Chapter 10 covers bipolar maintenance, where the LAI question differs from the schizophrenia question. Chapter 11 closes with the Indian decision frame: IPS CPG 2026, MHCA 2017, NLEM 2022, and the practical consent script.

Every clinical fact is anchored to either the Maudsley 15th edition (the canon), Wei et al. 2022 in JAMA Network Open (the strongest single piece of evidence shifting current practice), the IPS CPG 2026 (the current Indian guideline), the FGA and SGA pricing data from 1mg, PharmEasy and Apollo Pharmacy listings as of May 2026, or the published Indian cohort literature. Where the Notion source we extracted from had errors (the Maudsley year, the Wang versus Ostuzzi attribution on the 2024 SGA-LAI meta-analysis, the non-existent Kane Asia 2023 citation, the Spenzo manufacturer), the corrections are explicit in the reference list.

03 / CANON

Twelve Maudsley principles

The Maudsley Prescribing Guidelines, now in its 15th edition (Taylor, Barnes and Young; Wiley, 2025) remain the canonical reference for LAI prescribing in the English-language world. [3] Twelve principles from the LAI chapters carry most of the clinical weight and are reproduced or paraphrased verbatim below. The numbering is editorial; the content is Maudsley's.

01 **Give a test dose for all first-generation LAIs.** The recommended doses are: haloperidol decanoate 25 mg, flupentixol decanoate 20 mg, fluphenazine decanoate 12.5 mg (alternative 6.25 mg in elderly or sensitive patients), zuclopenthixol decanoate 100 mg. Wait at least one week between test dose and maintenance initiation.

02 **Begin with the lowest therapeutic dose.** Most LAIs are effective at doses lower than were historically prescribed. Higher initial doses do not produce faster onset and increase early-side-effect burden disproportionately.

03 **Administer at the longest possible licensed interval.** The Maudsley position is direct: "there is no evidence to suggest that shortening the dose interval improves efficacy." Shorter intervals raise costs and side-effect exposure without therapeutic benefit.

04 **Adjust doses only after an adequate period of assessment.** Steady state is reached at six to eight weeks for most LAIs and four to five months for paliperidone monthly. Dose adjustments inside that window are "illogical and impossible to evaluate properly" (Maudsley verbatim).

05 **LAIs are not recommended for antipsychotic-naive patients.** Tolerability of the same molecule must be established orally before depot exposure. The exception is the test-dose phase of an FGA, which is a small-dose tolerability check rather than a true exposure.

06 **Adding an oral antipsychotic to an LAI risks a high-dose prescription.** Combined regimens routinely produce total daily dose-equivalents above the licensed maximum, with no corresponding evidence of additional benefit and substantial added side-effect burden.

07 **Patients receiving fewer than twelve paliperidone monthly injections per year have an increased risk of relapse** (Maudsley verbatim). The corollary holds for all monthly LAIs: dose intervals must be honoured. Missed doses are not "make-up" doses.

08 **Aripiprazole LAI lacks the prolactin-related and metabolic adverse effects of other second-generation LAIs.** The Maudsley position frames this as the principal indication for preferring aripiprazole over paliperidone or risperidone in patients with prolactin-related side effects, metabolic syndrome, or both.

09 **Patients who refuse oral treatment and are acutely ill should not be given Risperdal Consta** (Maudsley verbatim). The three-week lag before therapeutic plasma levels appear means an acutely psychotic patient who refuses oral risperidone during the overlap will be effectively unmedicated for the first three weeks of LAI treatment.

10 **Prior safe use of olanzapine LAI does not imply low risk of post-injection syndrome** (Maudsley verbatim). Every injection of olanzapine pamoate carries the same approximately one-in-two-thousand risk of post-injection delirium and sedation syndrome. The three-hour observation requirement is per dose, not per patient.

11 **Among the FGA LAIs, zuclopenthixol decanoate has the observational edge.** Maudsley notes "some suggestion of an advantage for zuclopenthixol decanoate in terms of time to discontinuation and hospitalisation, but perhaps at the expense of a greater side-effect burden." The advantage is observational, not RCT-confirmed.

12 **Risperidone LAI and aripiprazole LAI have no effect on the risk of depressive recurrence** in bipolar disorder (Maudsley verbatim). They reduce manic recurrence. They do not protect against depressive episodes. This shapes LAI choice in bipolar maintenance.

04 / FGA

The public-sector pillars

The four first-generation depots are the working pharmacology of Indian public-sector psychiatry. They are cheap, familiar, available through DMHP and government tenders, and effective for D2-driven phenomenology. They carry the highest extrapyramidal burden of any LAI class. Their place in modern guidelines has narrowed, but their place in Indian practice has not. The order below tracks the Grover 2019 prescribing survey of 622 Indian psychiatrists.[8]

What the FGA tier does well

All four FGA depots are effective. The relapse-prevention literature has not produced a clear winner among them. The choice between them in Indian practice is driven by cost, supply, and side-effect-profile match to the patient. Fluphenazine is the default where cost is the binding constraint. Haloperidol is the default where the patient was previously on oral haloperidol with good response and where 4-week interval dosing is preferred over 2-week. Flupentixol is the choice where mild activation is desirable (anergic, negative-symptom-dominant chronic schizophrenia). Zuclopenthixol is the choice where sedation is desirable (chronically aggressive or agitated patient on long-term management).

What the FGA tier does badly

The trade-off is movement disorder. All four FGA depots have meaningfully higher rates of acute extrapyramidal symptoms, akathisia and tardive dyskinesia than the SGA LAIs. The Maudsley position is that "none of the individual LAI FGAs has emerged as clearly superior in efficacy" but all carry higher EPS burden than any SGA LAI. The clinical implication: where cost and supply allow, the SGA LAI is preferred for first-episode and younger patients precisely because the lifetime tardive dyskinesia risk on FGA depots accumulates over years.

01 / INDIAN USAGE 32.7%

Fluphenazine decanoate

ANATENSOL (PIRAMAL) · FLUDECAN · F-TENSIL · FLYZOX · GENERIC IP

TEST DOSE
12.5 mg IM (alt 6.25 mg in elderly)

MAINTENANCE
12.5 to 100 mg every 2 weeks

MAX LICENSED
100 mg every 2 weeks

INTERVAL
2 to 4 weeks

ORAL OVERLAP
1 to 2 weeks of oral fluphenazine

HALF-LIFE
7 to 14 days

STEADY STATE
~8 weeks

SITE
Gluteal

INDIAN PRICE
Rs 24 to 38 per 25 mg ampoule

NLEM 2022
Yes (only FGA LAI on NLEM)

The default depot of Indian public-sector practice. Available as Anatensol (Piramal Enterprises) and as multiple generic IP suppliers. Recommended monthly maintenance cost lands between 30 and 80 rupees, cheaper than any other LAI in India by an order of magnitude.

PHARMACOLOGY AND POSITIONING

A high-potency piperazine phenothiazine with the steepest D2 affinity curve among the FGA depots. The decanoate ester is dissolved in sesame oil; absorption from the gluteal depot is slow and predictable, with onset 24 to 72 hours and clinical effects lasting 2 to 4 weeks per dose. Two consequences follow from the receptor profile. First, the dose-response curve is steep, which makes under-dosing perilous: Kane and colleagues' 1983 randomised trial demonstrated 56% relapse on 1.25 to 5 mg every 2 weeks versus 7% relapse on 25 mg every 2 weeks at one year (cited Maudsley 14th edition). The standard dose is the dose; reducing below it to minimise side effects produces relapse at scale. Second, the absence of meaningful 5HT2A antagonism makes EPS burden high and predictable, particularly parkinsonism and akathisia.

INDIAN PRACTICE

The only FGA LAI on the National List of Essential Medicines 2022. Reliably supplied through District Mental Health Programme tenders. Multiple generic Indian Pharmacopoeia manufacturers (Divine Laboratories, Wellona Pharma, Ambica Pharma, Dellwich Healthcare) keep the cost floor low. Anatensol by Piramal is the dominant private-practice brand. F-Tensil, Fludecan and Flyzox are common generic alternatives. The 25 mg/mL × 1 mL ampoule is the only Indian strength; the 100 mg/mL high-strength formulation sold in some Western markets is not commonly available in Indian retail.

> **MAUDSLEY CANON**
>
> *For most patients the optimum dose is 25 mg every 2 weeks. Reduction below this is associated with substantially higher relapse rates than the standard dose.*

PITFALLS AND PEARLS

Under-dosing is the dominant prescribing error: clinicians chasing tolerability drop below 25 mg every 2 weeks and the relapse rate rises sharply. Sesame oil allergy is rare but consequential and contraindicates re-exposure to any sesame-oil-based depot. Depressogenic effect at higher doses is recognised; consider dose reduction if a depressive episode emerges on a stable dose. The test dose is 12.5 mg (alternative 6.25 mg in elderly or sensitive patients), with onset of effects often two-peaked (day of injection and a second slightly higher peak around one week later).

SPECIAL POPULATIONS

Pregnancy: avoid where possible; reproductive safety data limited. Breastfeeding: avoid. Elderly: start at 6.25 mg every 2 to 3 weeks; titrate slowly. Hepatic impairment: caution; plasma persistence may be prolonged. Renal impairment: no formal dose adjustment but observe.

02 / INDIAN USAGE 19.5%

Flupentixol decanoate

FLUANXOL DEPOT (LUNDBECK) · SPENZO DEPOT (INTAS) · PNXOL · FLUPEN

TEST DOSE
20 mg IM

MAINTENANCE
50 mg every 4 weeks to 300 mg every 2 weeks

MAX LICENSED
400 mg single dose

INTERVAL
2 to 4 weeks

ORAL OVERLAP
1 week of oral flupentixol

HALF-LIFE
8 days single, 17 days multiple

STEADY STATE
10 to 12 weeks

SITE
Buttock or thigh

INDIAN PRICE
Rs 97 to 437 per ampoule

NLEM 2022
No

Spenzo Depot is by Intas, not Sun Pharma as is sometimes recorded (a frequent and worth-correcting attribution error). Maintenance cost lands between 100 and 400 rupees a month. Lundbeck's Indian Fluanxol supply has been patchy on online channels in 2025 and 2026; physical pharmacy availability is better.

PHARMACOLOGY AND POSITIONING

A thioxanthene with mixed D1 and D2 antagonism plus partial 5HT2A antagonism that produces an activating clinical signature, in direct contrast to its sedating sister molecule zuclopenthixol. Onset of action 2 to 7 days; effect duration 3 to 4 weeks per dose at standard maintenance. The activating profile makes flupentixol useful in chronic schizophrenia presentations dominated by anergia, social withdrawal and negative symptoms; the same property makes it inappropriate in acutely agitated, excited or hostile patients in whom activation worsens the clinical picture. Maudsley flags "may have an activating effect (aggression or mood elevation)" alongside increased EPS compared to zuclopenthixol.

INDIAN PRACTICE

Two commercial brands dominate: Lundbeck's Fluanxol Depot (20 mg/mL × 1 mL and 40 mg/mL × 2 mL formats, giving 20 mg and 80 mg ampoule strengths respectively) and Intas's Spenzo Depot 20 (20 mg/mL × 1 mL). Pnxol and Flupen are smaller generic alternatives. Used widely in private practice and at tertiary centres including NIMHANS. The maximum licensed single dose of 400 mg is the highest of any LAI on the Indian market, providing flexibility for treatment-resistant chronic schizophrenia, though doses above 80 mg per 2 weeks are rarely needed in routine practice.

> **MAUDSLEY CANON**
> *May have activating effect (aggression or mood elevation) and increased extrapyramidal side effects compared to zuclopenthixol and SGAs. Not recommended in excitable or agitated patients.*

PITFALLS AND PEARLS

The most common prescribing error is initiating flupentixol in agitated patients in whom activation worsens hostility and arousal; reach for zuclopenthixol or a SGA depot instead. Test dose is 20 mg, then wait one week before the first maintenance dose; oral overlap is one week. Vehicle is vegetable oil (not sesame), so patients with sesame allergy who cannot use fluphenazine may be candidates here. The dose-conversion ratio against oral flupentixol is roughly: oral 2 to 3 mg per day equals depot 10 to 20 mg per week.

SPECIAL POPULATIONS

Pregnancy: avoid. Breastfeeding: avoid. Elderly: reduce initial dose 25 to 50% (start at 5 to 10 mg every 2 weeks). Hepatic impairment: caution; dose reduction may be needed. Concurrent QT-prolonging drugs: monitor with ECG (low QTc effect, less than 10 msec, but additive).

03 / INDIAN USAGE 17.8%

Haloperidol decanoate

MOVADOL LA (MOVA) · DOLTEUS (ALTEUS) · HALDOL DECANOATE (J&J, EXPORT) · GENERIC IP

TEST DOSE
25 mg IM

MAINTENANCE
50 to 200 mg every 4 weeks

MAX LICENSED
300 mg every 4 weeks

INTERVAL
4 weeks

ORAL OVERLAP
4 weeks of oral haloperidol

HALF-LIFE
18 to 21 days

STEADY STATE
~14 weeks

SITE
Gluteal only (licensed)

INDIAN PRICE
Rs 145 to 225 per 50 mg ampoule

NLEM 2022
No (only short-acting haloperidol 5 mg/mL listed)

The Indian generic supply is robust; brand availability fluctuates. Note: the Indian "Serenace" line is haloperidol lactate (short-acting IM and oral), not the decanoate. The brand-name distinction matters at the pharmacy counter.

PHARMACOLOGY AND POSITIONING

A butyrophenone with very high selective D2 affinity and minimal serotonergic, alpha-adrenergic or histaminergic activity. The decanoate ester in sesame oil produces slow release with onset of action 3 to 6 days after IM injection, peak plasma at 6 days (range 3 to 9), and a plasma half-life of approximately 21 days. Steady state reached at 8 to 12 weeks. Drug washout after discontinuation can take more than 6 weeks. The clinical niche is the patient who responded well to oral haloperidol and needs LAI conversion: pharmacodynamic continuity is direct because the molecule is unchanged.

INDIAN PRACTICE

Multiple Indian generic IP suppliers (Mova Pharmaceuticals, Alteus Biogenics, Jackson Laboratories, Dellwich Healthcare, Kabir Life Science) at roughly Rs 145 per 50 mg ampoule. Movadol LA (Mova) and Dolteus (Alteus) are the dominant Indian brand names. The Janssen originator Haldol Decanoate is referenced for export via GNH India but not routinely marketed in India. Conversion from oral: depot monthly dose equals 10 to 20 times the daily oral dose. A patient on 5 mg per day oral haloperidol switches to 50 to 100 mg every 4 weeks IM. Initial depot dose should not exceed 100 mg even if calculation suggests higher; if needed, administer 100 mg on Day 1 and the remaining dose 3 to 7 days later.

> **MAUDSLEY CANON**
>
> *Doses above 100 mg per 4 weeks have no additional effect in the published trials. Optimally effective at 75 mg per 4 weeks. Doses of 200 mg per month or more are supratherapeutic.*

PITFALLS AND PEARLS

Dose escalation past 100 mg per 4 weeks is the most common error in routine practice; supratherapeutic doses worsen EPS without improving efficacy. Continue oral haloperidol for the full 4 weeks after the first depot, the longest oral overlap among FGA depots. Baseline ECG is mandatory: moderate QTc effect (10 to 20 msec), more in older patients and on concurrent QT-prolonging drugs. The Serenace versus Movadol distinction is consequential; patients sometimes receive short-acting haloperidol instead of decanoate from undertrained pharmacy staff.

SPECIAL POPULATIONS

Pregnancy: the most studied LAI in pregnancy and the lowest-concern FGA depot for reproductive safety where an LAI is genuinely needed. Elderly: start at 25 to 50 mg every 4 weeks with ECG mandatory; risk of falls and postural hypotension. Hepatic impairment: caution. Parkinson's disease or dementia with Lewy bodies: contraindicated.

04 / INDIAN USAGE LESS THAN THE ABOVE THREE

Zuclopenthixol decanoate

CLOPIXOL DEPOT (LUNDBECK)

TEST DOSE
100 mg IM

MAINTENANCE
200 to 500 mg every 2 weeks

MAX LICENSED
600 mg every week (max single dose 600 mg)

INTERVAL
2 to 4 weeks (1 weekly licensed)

ORAL OVERLAP
3 weeks of oral zuclopenthixol

HALF-LIFE
17 to 21 days

STEADY STATE
10 to 12 weeks

SITE
Buttock or thigh (not deltoid)

INDIAN PRICE
Rs ~565 per 200 mg ampoule

NLEM 2022
No

The most expensive of the four FGA depots in India and the one with the most patchy supply. Single brand (Clopixol Depot, Lundbeck). Maintenance cost lands between 1,100 and 2,300 rupees per month.

PHARMACOLOGY AND POSITIONING

A thioxanthene with D1, D2 and 5HT2A antagonism; the sedating profile contrasts directly with flupentixol's activating effect. Onset of action 3 to 7 days; clinical effect duration 2 to 4 weeks per dose. Plasma half-life 17 to 21 days; steady state at 10 to 12 weeks. Maudsley observational data places zuclopenthixol decanoate at the top of the FGA LAI class for time-to-discontinuation and hospitalisation reduction, though no RCT confirms this. The clinical niche is the chronic schizophrenic patient with prominent aggression, irritability, hostility or impulsive behaviour on a long-term management plan.

INDIAN PRACTICE

Single brand (Clopixol Depot, Lundbeck) at the 200 mg/mL × 1 mL strength. No major Indian generic equivalent identified. Supply has been chronically patchy since 2020; physical pharmacy availability is more reliable than online retail. Used selectively in tertiary centres and forensic-adjacent settings. The maximum single licensed dose of 600 mg is the highest of any LAI globally, reflecting the molecule's tolerability margin at high doses; rarely needed in practice but available for treatment-resistant aggression.

> **MAUDSLEY CANON**
> *More sedating than flupentixol, therefore preferable in aggressive or agitated patients. Slightly better efficacy than other LAI FGAs in observational data, with the lowest discontinuation rate of the FGA depot class.*

PITFALLS AND PEARLS

The single most common error is confusion with zuclopenthixol *acetate* (Clopixol Acuphase), a short-acting tranquillising preparation (24 to 72 hour duration) used for acute behavioural emergencies. The *decanoate* (Clopixol Depot) is the long-acting maintenance form. Both are Lundbeck-branded but distinct products with different licences. Test dose is 100 mg, then wait at least 1 week. Continue oral zuclopenthixol for 3 weeks after first depot. Deltoid administration is not recommended due to formulation volume and viscosity; gluteal only.

SPECIAL POPULATIONS

Pregnancy: avoid. Elderly: reduce to a quarter or half of usual adult dose; start at 50 to 100 mg every 2 weeks. Hepatic impairment: caution; dose reduction may be needed. Cardiovascular disease: low QTc effect (less than 10 msec) makes this a safer FGA in patients with cardiac comorbidity.

05 / SGA

The private-sector frontier

The four second-generation injections form the private-sector and tertiary-centre tier of Indian LAI practice. The cost ladder runs steeply through this group. Sun Pharma's Paliris LA, launched as a generic of Invega Sustenna, and Torrent's Tolaz LA olanzapine pamoate have been the single most significant shifts in Indian SGA LAI access in the last five years. The order below tracks Indian use frequency.

What the SGA tier does well

Lower extrapyramidal burden across the class. Lower tardive dyskinesia risk over years of treatment. Better tolerability and adherence over time, with the two linked. Longer dose intervals (monthly versus the 2-week FGA standard) reduce clinic burden. The new-patient and first-episode position has shifted toward SGA LAIs over the last decade, both in Maudsley 15th and IPS CPG 2026. The metabolic and prolactin trade-offs are real but molecule-specific within the SGA tier.

What the SGA tier does badly in India

Cost remains the dominant barrier even after the Sun and Torrent generics. Aripiprazole monohydrate remains import-only via GNH India and effectively out of reach for most patients. Prolactin elevation on paliperidone and risperidone limits use in young women and men sensitive to sexual side effects. Metabolic burden on Tolaz LA accumulates over years; baseline and periodic monitoring of weight, fasting glucose, HbA1c and lipids is mandatory. The PDSS observation requirement on Tolaz LA is the binding logistic constraint that effectively rules the molecule out of routine outpatient practice; tertiary centres with the infrastructure can use it as a defensible first-line choice on cost grounds.

05 / MOST USED SGA LAI IN INDIA

Paliperidone palmitate, one-monthly (PP1M)

INVEGA SUSTENNA (J&J) · PALIRIS LA (SUN PHARMA, GENERIC)

TEST DOSE
Not required (oral risperidone 3-day trial desirable)

LOADING REGIMEN
Day 1: 150 mg deltoid. Day 8 (plus or minus 4): 100 mg deltoid.

MAINTENANCE
25 to 150 mg monthly

MAX LICENSED
150 mg monthly

INTERVAL
Monthly (plus or minus 7 days from dose 3 onward)

ORAL OVERLAP
None required pharmacokinetically (Maudsley notes oral risperidone 7+ days bridge reduces hospital days)

HALF-LIFE
25 to 49 days

STEADY STATE
~5 months

SITE
Initiation deltoid; maintenance deltoid or gluteal

INDIAN PRICE
Paliris LA Rs 2,431 to 3,184; Invega Sustenna Rs 5,039 to 5,793

The Maudsley default SGA LAI for new patients, on grounds of monthly interval (versus 2-weekly for Risperdal Consta), no cold-chain requirement, no oral overlap with loading regimen followed, and deltoid administration. Sun Pharma's Paliris LA generic dropped the Indian floor from about five thousand rupees a month to two to three thousand.

PHARMACOLOGY AND POSITIONING

The active metabolite of risperidone (9-hydroxyrisperidone); a benzisoxazole derivative formulated as an aqueous suspension of palmitate ester nanocrystals. The molecule has the same D2 and 5HT2A antagonism as risperidone with broadly comparable receptor binding profile, but the palmitate-ester pharmacokinetics produce a different release shape: rapid initial absorption (Tmax 13 days), then a sustained plateau that holds through to the next monthly dose. Improvement can be seen as early as day 4 after the first injection in some patients. Maudsley positions this as the default SGA LAI for new patients on grounds of monthly interval, deltoid administration, no oral overlap with loading, and tolerability profile.

INDIAN PRACTICE

Two products dominate: Janssen India's Invega Sustenna (originator, 50/75/100/150 mg prefilled syringes; MRP Rs 5,039 to 5,793 per syringe at the upper strengths) and Sun Pharma's Paliris LA (Indian generic, launched circa 2020; same strength options at Rs 2,431 to 3,184 per syringe). Bioequivalence study against Invega Sustenna 156 mg published in J Neuropsychiatry; clinical performance considered equivalent. The Sun generic collapsed the Indian cost floor by roughly half and is now the most prescribed SGA LAI in Indian private practice. Available reliably in metros, tier-1 cities, and most large private hospitals; cold-chain transport required.

> **MAUDSLEY CANON**
>
> *Patients receiving fewer than 12 injections a year have an increased risk of relapse. Correct dosing is critical to the effectiveness of paliperidone monthly.*

PITFALLS AND PEARLS

"Monthly" dosing is calendar-monthly, not every 28 days; the 28-day interval gives 13 doses per year rather than 12, and the Maudsley relapse warning specifies the 12-per-year threshold. Loading regimen must use deltoid administration (Day 1: 150 mg deltoid; Day 8: 100 mg deltoid); gluteal initiation produces lower Cmax and is not licensed for loading. When switching a stable patient from another LAI to paliperidone, skip the loading regimen and start at the calculated equivalent maintenance dose, deltoid or gluteal. Trevicta (PP3M, not available in India) plasma persistence after a single dose extends up to 18 months; the implication carries to PP1M planning in women of childbearing age who may later switch to PP3M.

SPECIAL POPULATIONS

Pregnancy and lactation: avoid where possible; the long plasma persistence is the operative concern. Renal impairment (creatinine clearance 50 to 80 mL/min): dose-reduce to 50 mg Day 1, 25 mg Day 8, then 25 to 75 mg monthly. Severe renal impairment (CrCl below 50): avoid. Elderly: start at the lower end of the dose range. Prolactin-sensitive patients: switch to aripiprazole (oral or LAI).

06 / HISTORIC INDIAN SGA LAI ANCHOR, DECLINING

Risperidone microspheres (Risperdal Consta)

RISPERDAL CONSTA (JANSSEN, JOHNSON & JOHNSON)

TEST DOSE
Not required; oral risperidone tolerability mandatory

INITIATION
25 mg IM every 2 weeks; titrate to 37.5 or 50 mg as needed

MAINTENANCE
25 to 50 mg every 2 weeks

MAX LICENSED
50 mg every 2 weeks

INTERVAL
Every 2 weeks only (longer intervals not licensed)

ORAL OVERLAP
3 weeks minimum; sometimes 6 to 8 weeks (Maudsley)

HALF-LIFE
4 days terminal; effect persists ~5 weeks

STEADY STATE
6 to 8 weeks

SITE
Deltoid or gluteal; refrigerated storage required

INDIAN PRICE
Rs 3,733 to 5,500 per dose (effectively Rs 7,400 to 11,000 per month)

Indian usage has declined since Paliris LA launched. The patient currently stable on Consta is not switched without indication; the new patient is not started on it. The Maudsley reposition (continuation only, new patients to paliperidone) is the current canon.

PHARMACOLOGY AND POSITIONING

Risperidone encapsulated in microspheres of polyglactin, a biodegradable polymer; provided as powder plus diluent that must be reconstituted immediately before use. Two-step release pattern: minimal release in days 1 to 3, then a major release starting around day 20 and peaking at approximately day 28. The 3-week pharmacokinetic lag before therapeutic plasma levels appear is the molecule's defining clinical feature and the single largest barrier to its use. Plasma half-life is 4 days terminal but the depot effect persists approximately 2 weeks; steady state at 6 to 8 weeks; plasma levels drop below steady state by 5 weeks after the last dose, near baseline by 7 to 8 weeks.

INDIAN PRACTICE

Marketed by Janssen India / Johnson & Johnson at 25, 37.5 and 50 mg per vial (each with 2 mL diluent). MRP Rs 3,733 to 5,500 per dose; effective monthly cost Rs 7,400 to 11,000 at maintenance dosing. The historic Indian SGA LAI anchor through NMHP formulary inclusion in the 2010s. Usage has eroded since Paliris LA launched because paliperidone offers monthly dosing without cold chain or oral overlap. Cold-chain storage at refrigerated temperature is required at every link in the supply chain. Refrigerated reconstitution before each use. Available in metros and tier-1 cities through large pharmacy chains and hospital pharmacies.

> **MAUDSLEY CANON**
>
> *For continuation of established patients only. New patients should be initiated on paliperidone in preference to risperidone. Patients who refuse oral treatment and are acutely ill should not be given Risperdal Consta because of the long delay in drug release.*

PITFALLS AND PEARLS

Three-week oral overlap is non-negotiable; sometimes 6 to 8 weeks per Maudsley. The acutely psychotic non-adherent patient who refuses oral cover after Consta initiation is effectively untreated for the first 3 weeks, which is when relapse risk is highest. Missed-dose double-dosing produces toxic plasma levels 3 to 5 weeks later because of the late release peak. Switching out of Consta requires waiting 2 to 4 weeks after the last RLAI dose was *due* (i.e. 4 to 6 weeks after the last actual injection) before starting the new LAI, because the late Consta peak would otherwise stack on the new agent's initiation phase. The 50 mg cap is the licensed maximum; trial doses to 75 mg exceeded licence.

SPECIAL POPULATIONS

Pregnancy: avoid. Lactation: avoid. Renal impairment: dose-adjust as for oral risperidone (start low, titrate cautiously). Hepatic impairment: caution. Cold-chain failure: the dose must be discarded; do not administer if cold chain was broken.

07 / AVAILABLE IN INDIA AS TORRENT GENERIC

Olanzapine pamoate

TOLAZ LA (TORRENT PHARMACEUTICALS) · 210 / 300 / 405 MG VIALS

TEST DOSE
Not required (oral olanzapine tolerability required)

MAINTENANCE
150 to 300 mg every 2 weeks or 300 to 405 mg every 4 weeks

MAX LICENSED
300 mg every 2 weeks

INTERVAL
2 or 4 weeks

ORAL OVERLAP
Not required (peak in 2 to 4 days)

HALF-LIFE
~30 days

STEADY STATE
~12 weeks

SITE
Gluteal only (deltoid less effective per Maudsley)

PDSS OBSERVATION
Three hours post-injection, in clinical setting (EU SmPC mandate)

INDIAN PRICE
Rs 1,206 (210 mg) / Rs 1,458 (300 mg) / Rs 1,591 to 2,240 (405 mg)

Torrent's Tolaz LA is the dominant Indian olanzapine pamoate brand. Cheapest SGA LAI in India by per-month cost. The binding constraint on routine use is not cost or availability but the three-hour post-injection observation infrastructure that PDSS demands.

PHARMACOLOGY AND POSITIONING

A pamoate (4,4'-methylenebis-3-hydroxy-2-naphthoate) salt of olanzapine, formulated as a lyophilised powder reconstituted in sterile water at the point of use. The resulting suspension dissolves slowly from the gluteal IM site over 2 to 4 weeks; peak plasma at 2 to 7 days; effective half-life 30 to 57 days; steady state at 3 to 4 injections (approximately 12 weeks). Low EPS and tardive dyskinesia burden compared to FGA depots and risperidone or paliperidone (a key advantage). Metabolic burden cumulative and high. Deltoid administration is licensed in some jurisdictions but Maudsley cites Mitchell 2013 finding deltoid less effective; gluteal is the licensed Indian route.

INDIAN PRACTICE

Torrent Pharmaceuticals' Tolaz LA is the dominant Indian brand at 210, 300 and 405 mg vials (the international Zyprexa Relprevv strengths). Retailed on 1mg, PharmEasy, Practo, Truemeds and GNH India. Indian per-vial prices: Rs 1,206 to 1,328 (210 mg), Rs 1,458 (300 mg), Rs 1,591 to 2,240 (405 mg). At typical maintenance dosing (300 mg every 4 weeks), monthly cost is around Rs 1,458, making this the cheapest SGA LAI in India by per-month cost. The Indian tertiary-care experience (Sharma 2020) reports 300 mg every 2 weeks as the most common dose (55% of cases), 405 mg every 4 weeks next (32.5%). Three published Indian PDSS case reports confirm real clinical use. [10]

> **MAUDSLEY CANON**
> *Prior safe use of olanzapine LAI does not imply low risk of post-injection syndrome. Every injection carries the same approximately one-in-two-thousand risk of post-injection delirium and sedation syndrome.*

PITFALLS AND PEARLS

The three-hour post-injection observation requirement is per dose, not per patient. PDSS incidence is approximately 0.044% of injections (1 in 2,272); 86 to 91% of reactions occur within the first hour of injection. Olanzapine plasma levels in the syndrome may reach 600 mcg per litre (substantially supratherapeutic). Confusion with short-acting Oliza (Intas) and Oleanz (Sun Pharma) 10 mg ampoules is common and consequential, since both are olanzapine but at 10 mg per ampoule for acute agitation rather than the depot 210/300/405 mg vials. Metabolic monitoring (weight, fasting glucose, HbA1c, lipid panel) at baseline and every 3 months is mandatory. New olanzapine LAI molecules in clinical trials (TEV-44749, olanzapine subcutaneous) report no PDSS in phase 3; an Indian filing for the new formulation has not been announced.

SPECIAL POPULATIONS

Pregnancy: avoid. Lactation: avoid. Elderly: start at lower doses (150 mg every 2 weeks or 210 mg every 4 weeks); PDSS monitoring particularly important. Hepatic impairment: caution; periodic liver function monitoring. Diabetes or pre-diabetes: high metabolic burden makes this molecule a poor first choice; consider aripiprazole if available.

08 / IMPORT-ONLY, PREMIUM PRICING

Aripiprazole monohydrate (Abilify Maintena)

ABILIFY MAINTENA (OTSUKA / LUNDBECK, IMPORTED VIA GNH INDIA)

TEST DOSE
Not required; oral aripiprazole 10 mg/day for 14 days to establish tolerability

INITIATION
One-injection: 400 mg + oral aripiprazole 10 to 20 mg/day for 14 days. Two-injection: two separate 400 mg + single 20 mg oral.

MAINTENANCE
300 to 400 mg per calendar month

MAX LICENSED
400 mg per month

INTERVAL
Monthly (calendar date)

HALF-LIFE
30 days (300 mg), 47 days (400 mg)

STEADY STATE
~20 weeks

SITE
Deltoid or gluteal; needle length adjusted for BMI

INDIAN AVAILABILITY
Import-only via GNH India; no domestic CDSCO marketing authorisation

INDIAN PRICE
Effectively out of reach; quoted on import request

FDA-approved for bipolar I maintenance monotherapy: the only LAI in India (and the only LAI globally outside the newer 2-monthly Asimtufii) with that indication. Indian availability is the binding constraint: import-only via GNH India, no domestic generic, monthly cost typically exceeds median Indian household monthly income.

PHARMACOLOGY AND POSITIONING

A partial D2 agonist with approximately 30 to 40% intrinsic activity; partial 5HT1A agonist; potent 5HT2A antagonist; high D3 affinity. The partial-agonism mechanism produces the molecule's distinguishing clinical signature: low prolactin (often lowered, not raised), minimal metabolic burden, minimal sedation. The trade-off is akathisia, the dose-limiting adverse effect in the first 4 to 8 weeks of treatment, and impulse-control disorders (gambling, hypersexuality) reported rarely but consequentially. Lyophilised microsphere suspension reconstituted before use; slow release over the monthly interval. Tmax around 4 days deltoid / 7 days gluteal; effective half-life 30 days (300 mg) or 47 days (400 mg); steady state at 4 to 5 months.

INDIAN PRACTICE

Import only via GNH India and similar specialty distributors. No domestic CDSCO marketing authorisation. No Indian generic. The only LAI in India with FDA approval for bipolar I maintenance monotherapy. Used in select tertiary centres and large private hospitals for two principal indications: prolactin-sensitive patients in whom paliperidone or risperidone produce intolerable sexual dysfunction or amenorrhoea, and metabolic-sensitive patients in whom olanzapine pamoate carries unacceptable weight and glucose risk. The two-month formulation (Abilify Asimtufii, FDA April 2023) is not in India.

> **MAUDSLEY CANON**
> *Aripiprazole lacks the prolactin-related and metabolic adverse effects of other SGA LAIs and so is a useful alternative to them.*

PITFALLS AND PEARLS

Akathisia in the first 4 to 8 weeks is the most common reason patients drop the molecule; if it emerges, consider reducing from 400 mg to 300 mg monthly before switching molecules. Adjunct propranolol or low-dose lorazepam manages the akathisia; avoid adding an oral SGA as it defeats the purpose of the LAI. The two-injection-start regimen (two separate 400 mg + single 20 mg oral) is preferred over the one-injection-start (400 mg + 14 days oral) in patients new to oral aripiprazole; the one-injection-start is reserved for patients already stabilised orally. Strong CYP2D6 or CYP3A4 inhibitors or inducers (rifampicin, carbamazepine, certain antifungals and antiretrovirals) for more than 14 days require dose adjustment.

SPECIAL POPULATIONS

Pregnancy: limited data; oral aripiprazole considered relatively safe and is the most reasonable LAI for women of childbearing potential when an LAI is genuinely needed. Elderly (over 65): use the one-injection-start regimen only (not the two-injection). Renal or hepatic impairment: no dose adjustment per SmPC. Concurrent CYP modulators: adjust dose over 14 days; the 200 mg per month dose is reserved for patients on enzyme inhibitors.

What is coming next

Three shifts in the Indian SGA LAI landscape are worth tracking. First, **Lupin's risperidone LAI** received United States FDA approval in November 2025 with 180-day competitive generic therapy exclusivity, using its proprietary Nanomi PrecisionSphere platform. This is the first long-acting injectable antipsychotic from an Indian sponsor to receive FDA approval. Lupin has not yet announced an Indian regulatory filing, but the platform technology could extend to paliperidone or aripiprazole generics in the next 2 to 3 years. Second, **Tolaz LA pricing** at around 1,500 to 3,200 rupees per month makes olanzapine pamoate the cheapest SGA LAI in India by per-month cost; if the PDSS observation infrastructure expands in tertiary centres and large private hospitals, uptake could grow substantially. Third, **Sun Pharma's Paliris LA** has stabilised paliperidone pricing at roughly half the originator's level, and the field is watching for the next molecule a domestic Indian generic will discount. The likeliest candidate over the next 5 years is paliperidone three-monthly (Trinza) if CDSCO marketing authorisation is granted, which would close the dose-interval gap that currently caps the Indian formulary at monthly dosing.

> THE SGA TIER IN 2026, IN ONE PARAGRAPH
>
> The Indian SGA LAI tier is structurally bifurcated: domestic generics have collapsed the cost barrier for paliperidone (Paliris LA by Sun) and olanzapine pamoate (Tolaz LA by Torrent), bringing both molecules into the 1,500 to 3,200 rupees per month range. Risperidone microspheres (Risperdal Consta) remain at roughly 7,500 to 11,000 rupees per month and have lost ground to paliperidone in new initiations. Aripiprazole monohydrate (Abilify Maintena) is import-only via GNH India at premium pricing and remains the molecule of last resort for prolactin-sensitive or metabolic-sensitive patients who can afford it. The four molecules cover most of the clinical scenarios that international guidelines anticipate; the structural gaps are at the dose-interval frontier (no PP3M, no PP6M, no Asimtufii) and at the infrastructure layer (PDSS observation for Tolaz LA limits its use even where cost is favourable).

06 / ABSENT

Six formulations India does not have

The international LAI literature now treats six formulations as routine or near-routine that the Indian formulary does not list. Two of these are the longer-interval paliperidone formulations. Two are extended aripiprazole formulations. Two are newer risperidone formulations using non-microsphere release technologies. The Indian patient who would benefit most from a quarterly or biannual schedule cannot have one. The gap is structural.

FORMULATION	INTERVAL	YEAR	INDIAN STATUS
PALIPERIDONE PALMITATE THREE-MONTHLY (INVEGA TRINZA)	3 months	FDA 2015	No CDSCO marketing authorisation. Available only by individual import via GNH India. No domestic retail listing.
PALIPERIDONE PALMITATE SIX-MONTHLY (INVEGA HAFYERA, BYANNLI)	6 months	FDA 2021, EMA 2022	**Explicitly rejected by CDSCO Subject Expert Committee, May 2022.** J&J's import-and-manufacture proposal was declined on grounds of "no unmet need." Status unchanged at time of writing.
ARIPIPRAZOLE LAUROXIL (ARISTADA)	Monthly, 6-weekly, or 2-monthly	FDA 2015	Alkermes product, United States only. No filing in India. Aristada Initio (nanocrystal loading dose) similarly United States only.
ARIPIPRAZOLE 2-MONTHLY (ABILIFY ASIMTUFII)	2 months	FDA April 2023	Otsuka and Lundbeck's once-every-2-months aripiprazole. Approved for schizophrenia and bipolar I maintenance. Not in India.
RISPERIDONE SUBCUTANEOUS (PERSERIS, UZEDY)	Monthly (Perseris); monthly or 2-monthly (Uzedy)	FDA 2018 (Perseris), 2023 (Uzedy)	United States only. Subcutaneous administration. Resolves Consta's cold-chain, oral-overlap and lag-time limitations. No Indian filing.
RISPERIDONE ISM, RYKINDO	Monthly IM	FDA 2023 (Rykindo)	Risperidone ISM (Risvan/Doria in EU) and Rykindo (US generic IM): not in India.

What the six absences cost

The principal clinical loss is the dose-interval frontier. A patient stable on paliperidone monthly for one year has, in Indian practice, no option to graduate to three-monthly or six-monthly. The Maudsley 15th edition position is that the patient stable on PP1M for at least four months on the same dose for the last two months can switch to PP3M; the patient stable on PP3M for at least one cycle can switch to PP6M. Each step reduces injection burden, clinic visit frequency, and total annual cost (despite higher per-dose pricing). The Indian formulary stops at monthly. The clinical implication is that Indian patients on long-term LAI maintenance receive twelve injections per year where European patients receive four or two.

The Lupin wildcard

Lupin received United States FDA approval in November 2025 for a generic risperidone LAI microsphere product, manufactured on its proprietary Nanomi PrecisionSphere platform, with 180-day competitive generic therapy exclusivity in the United States. This is the first long-acting injectable antipsychotic from an Indian sponsor to receive FDA approval. The Indian launch timeline is not yet announced. If Lupin extends the platform to paliperidone or aripiprazole, or if the company files Indian regulatory dossiers for its risperidone product, the Indian SGA LAI landscape could shift in 2026 or 2027. The wildcard is worth tracking.

> THE CDSCO POSITION ON SIX-MONTHLY PALIPERIDONE
>
> The Subject Expert Committee meeting of 12 May 2022 declined J&J's proposal to import and manufacture Invega Hafyera at 700 mg and 1000 mg strengths. The Committee's reasoning, on the public record, was that the proposal demonstrated no unmet need in India, that comparative efficacy data against PP1M and PP3M in Indian patients had not been provided, and that the list of countries approving PP6M without prior PP3M approval had not been documented. The status remained unchanged at time of writing. The clinical interpretation: until PP3M is approved and stocked in India, PP6M cannot follow.

What each absence costs clinically

The absence of **PP3M** caps the Indian formulary at monthly dosing for paliperidone. A patient stable on PP1M for one year has, in European or American practice, the option to graduate to PP3M at the same total annual dose, with one quarterly injection replacing three monthly ones. The Indian patient receives twelve injections per year regardless. For patients with poor venous tolerance, work schedules that make monthly clinic visits difficult, or rural addresses requiring half-day travel to the prescribing centre, the cost is concrete.

The absence of **PP6M** caps the formulary at the quarterly frontier. The 4-year mirror-image studies cited in Maudsley 15th edition support PP6M as a stable maintenance regimen for patients with at least 12 months of prior PP1M or PP3M exposure. Indian patients on long-term LAI maintenance, particularly those with stable but persistent illness who would benefit from minimal clinic contact, have no analogous option.

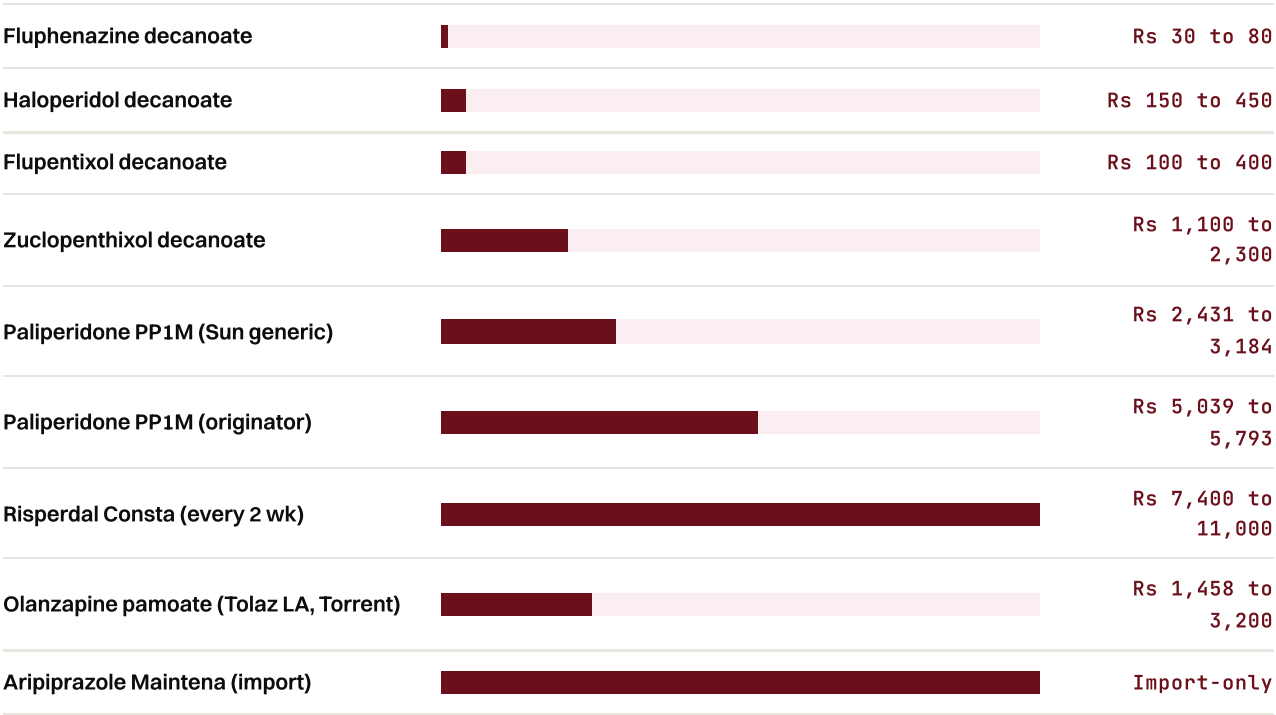
The absence of **Aristada and Asimtufii** caps the aripiprazole formulary at monthly dosing for Maintena. Aristada's flexibility (monthly, 6-weekly, or 2-monthly intervals) and Asimtufii's bi-monthly schedule both address the dose-interval frontier from the aripiprazole side. Without them, the Indian patient who tolerates aripiprazole and benefits from its prolactin-and-metabolic-sparing profile receives 12 injections per year where their European or American counterpart could receive 6 or 9.

The absence of **Perseris, Uzedy and Rykindo** caps the risperidone formulary at the microspheres-with-oral-cover regimen. Uzedy and Rykindo were designed specifically to eliminate Consta's three biggest constraints (cold-chain dependence, oral overlap, two-weekly interval). Indian patients on risperidone LAI continue to face all three.

07 / COST

The Indian cost ladder

The single largest determinant of LAI choice in Indian practice is monthly cost. The ladder below shows the realistic 2026 retail monthly cost of maintenance for each of the LAIs in routine Indian commerce. The bar lengths are scaled to the cost. Prices are from 1mg, Apollo Pharmacy, MedPlus, PharmEasy and IndiaMart institutional listings at time of writing. Government supply (DMHP) covers only fluphenazine reliably.



What this ladder means clinically

The Indian minimum wage in 2026 sits around 8,000 to 12,000 rupees per month depending on state and category. The fluphenazine ladder rung is 0.3% to 0.7% of monthly minimum wage. The Risperdal Consta rung is 90% to 130%. The same molecule with the same evidence base costs the patient at one end of the ladder, in monthly terms, what the patient at the other end of the ladder earns. Insurance coverage does not change this in most Indian outpatient settings. CGHS reimburses listed drugs only; modern SGA LAIs frequently require special sanction. Ayushman Bharat (PMJAY) covers in-patient packages and bundled drug costs but not outpatient LAI maintenance. The cost ladder is the choice ladder for most Indian patients.

> THE CLINICAL IMPLICATION
>
> The decision tree in Indian practice runs cost-first, not pharmacology-first. The patient who can afford 200 rupees a month gets fluphenazine or haloperidol decanoate. The patient who can afford 3,000 rupees a month gets Paliris LA or Tolaz LA. The patient who can afford 11,000 rupees a month gets Risperdal Consta or paliperidone originator. The pharmacological niches (aripiprazole for prolactin-sensitive, olanzapine pamoate for adherence-anchored monthly dosing where PDSS monitoring is available) are realised only for the minority of patients with either tertiary care access or sustained personal expenditure capacity. The cost ladder is also the side-effect ladder: the cheapest LAIs carry the highest extrapyramidal burden. This is the public-health face of the aporia.

The annual cost arithmetic

Twelve months of LAI maintenance, at typical doses, lands in startlingly different brackets. Fluphenazine 25 mg every 2 weeks across a year is roughly 720 rupees of drug cost. Haloperidol decanoate 100 mg every 4 weeks is 1,800 to 2,700 rupees a year. Zuclopenthixol 200 mg every 2 weeks is 13,200 rupees a year. Paliris LA 100 mg monthly is around 29,000 rupees a year. Tolaz LA 300 mg every 4 weeks is around 17,500 rupees a year. Invega Sustenna 150 mg monthly is around 70,000 rupees a year. Risperdal Consta 37.5 mg every 2 weeks is around 100,000 to 120,000 rupees a year. The cheapest annual maintenance is 0.6% of the costliest. For perspective: India's nominal per-capita GDP in 2026 sits around 250,000 rupees, the median monthly household income in Tier 2 and Tier 3 cities around 25,000 to 40,000 rupees, and median schizophrenia-affected household monthly income substantially lower because of illness-related income loss. The Consta annual cost is one-third of median household annual income for the population that most needs LAI treatment.

The Sun Paliris LA generic shifted the SGA LAI floor from a Consta-anchored 100,000 rupees a year to a Paliris-anchored 30,000. Tolaz LA shifted it further, to 17,500 rupees a year at standard 300 mg every 4 weeks dosing. For patients with tertiary care access for the PDSS observation, Tolaz LA can offer the SGA tolerability profile at the FGA-tier cost. The trade-off is not financial; it is the three-hour observation infrastructure.

08 / OVERLAP

The oral overlap matrix and dose equivalence

Two practical tables anchor every initiation decision: which LAIs require oral overlap and for how long, and what daily oral dose each LAI maintenance dose corresponds to. The first table is operational. The second is conversion.

Oral overlap requirements

LAI	ORAL OVERLAP	REASON
FLUPHENAZINE DECANOATE	1 to 2 weeks	Delayed peak (8 to 12 days); test dose first
HALOPERIDOL DECANOATE	4 weeks	Peak 3 to 9 days, steady state at 14 weeks; longest overlap among FGAs
FLUPENTIXOL DECANOATE	1 week	Peak 4 to 7 days
ZUCLOPENTHIXOL DECANOATE	3 weeks	Peak 4 to 9 days but slow titration; covers extended initiation
RISPERIDONE MICROSPHERES (CONSTA)	**3 weeks minimum; sometimes 6 to 8**	Two-step release pattern; main release at week 3 to 4. Maudsley: patients refusing oral cover and acutely ill should not receive Consta.
PALIPERIDONE PALMITATE PP1M	**None required** (loading regimen)	Day 1 150 mg + Day 8 100 mg deltoid achieves therapeutic levels. Maudsley notes 7+ days oral risperidone bridge reduces hospital days.
OLANZAPINE PAMOATE	None required	Peak in 2 to 4 days; loading doses where needed
ARIPIPRAZOLE MONOHYDRATE (MAINTENA)	2 weeks (or single-day initiation regimen)	Slow release; peak plasma at week 1 deltoid; steady state at 4 to 5 months

Equivalent doses, first-generation LAIs

ORAL	DAILY ORAL DOSE	LAI	LAI DOSE
HALOPERIDOL	5 mg/day	Haloperidol decanoate	50 to 100 mg every 4 weeks
FLUPHENAZINE	5 to 10 mg/day	Fluphenazine decanoate	12.5 to 25 mg every 2 to 3 weeks
FLUPENTIXOL	3 to 5 mg/day	Flupentixol decanoate	20 to 40 mg every 2 to 3 weeks
ZUCLOPENTHIXOL	20 to 30 mg/day	Zuclopenthixol decanoate	200 to 400 mg every 2 weeks

FGA LAI depot doses are typically calculated as 10 to 20 times the daily oral dose, adjusted for tolerability and patient response.

Equivalent doses, second-generation LAIs

ORAL	DAILY ORAL	LAI	LAI DOSE
RISPERIDONE	2 mg/day	Risperidone microspheres	25 mg every 2 weeks
RISPERIDONE	3 mg/day	Risperidone microspheres	37.5 mg every 2 weeks
RISPERIDONE	4 mg/day	Risperidone microspheres	50 mg every 2 weeks
PALIPERIDONE	3 to 6 mg/day	Paliperidone palmitate (PP1M)	75 to 150 mg monthly
OLANZAPINE	10 mg/day	Olanzapine pamoate	150 mg every 2 weeks or 300 mg every 4 weeks
OLANZAPINE	15 mg/day	Olanzapine pamoate	210 mg every 2 weeks or 405 mg every 4 weeks
OLANZAPINE	20 mg/day	Olanzapine pamoate	300 mg every 2 weeks
ARIPIPRAZOLE	10 to 20 mg/day	Aripiprazole monohydrate	300 to 400 mg monthly

SGA LAI dose conversions are not linear; use manufacturer guidance and clinical response to titrate. Paliperidone palmitate three-monthly conversion (where available) is 3.5 times the last PP1M dose: PP1M 50 to PP3M 175, PP1M 75 to PP3M 263, PP1M 100 to PP3M 350, PP1M 150 to PP3M 525. PP6M conversion (where available) is PP3M 350 to PP6M 700, PP3M 525 to PP6M 1000.

Switching between LAIs

The Maudsley general rule for LAI-to-LAI switching is to give the new depot on the due date of the next dose of the original depot, in place of the original dose, at the equivalent dose calculated through the conversion tables above. Do not give an additional dose of the original; do not double-dose. Three exceptions are worth holding.

Risperdal Consta to anything. Consta has a post-dose peak at week 5. Switching out of Consta requires waiting 2 to 4 weeks after the last RLAI dose was *due* (i.e. 4 to 6 weeks after the last actual injection) before starting the new LAI, because the late Consta peak would otherwise stack on top of the new agent's initiation phase. The Maudsley caution is explicit on this and it is the single most common LAI-switching error in routine practice.

Anything to paliperidone palmitate. The PP1M loading regimen (Day 1: 150 mg deltoid; Day 8: 100 mg deltoid) is designed to bring plasma levels rapidly to therapeutic range, but if the patient is already at therapeutic levels on another LAI, the standard loading can produce supratherapeutic Cmax and akathisia. Maudsley's practical position: when switching from a stable patient on another LAI to paliperidone, skip the loading regimen and start at the calculated equivalent maintenance dose monthly, deltoid or gluteal.

FGA depot to olanzapine pamoate. Olanzapine pamoate's tolerability profile is meaningfully different (low EPS, high metabolic). The transition over 6 to 8 weeks allows the FGA depot to wash out while the new molecule reaches steady state. Expect transient irritability and sleep disturbance during week 2 to 4 of the switch as the dopaminergic environment shifts from saturated D2 antagonism to the olanzapine 5HT2A:D2 ratio profile. Counsel the patient and family in advance.

Missed doses and re-initiation

The handling of missed LAI doses is one of the most under-taught topics in clinical psychiatry. Maudsley provides molecule-specific guidance; the principles are: never double-dose, calculate the gap from the missed dose date, and either resume at maintenance (short gap) or re-initiate with loading (long gap).

Paliperidone PP1M: Maudsley reminds clinicians that "patients receiving fewer than 12 injections a year have an increased risk of relapse." If a PP1M dose is up to 6 weeks late (i.e. within 2 weeks of the scheduled monthly dose), resume the maintenance dose. If 6 weeks to 6 months late, re-initiate with Day 1 100 mg deltoid + Day 8 100 mg deltoid, then resume monthly. If more than 6 months late, treat as a new patient: full loading regimen (Day 1: 150 mg + Day 8: 100 mg).

Aripiprazole Maintena: If 5 to 6 weeks since last injection, resume maintenance. If 6 to 7 weeks, give next dose with one-day oral aripiprazole 20 mg supplementation. If more than 7 weeks (so more than 4 weeks late on the calendar-monthly schedule), re-initiate with the one-injection-start regimen including 14 days of oral aripiprazole.

FGA decanoates: If the gap is less than half the dose interval, resume maintenance. If between half and one full interval, give the missed dose at the next visit. If more than one full interval, give a half-dose at the next visit and resume the schedule. For haloperidol decanoate specifically, the long half-life (21 days) provides forgiveness; for fluphenazine decanoate (7 to 14 days), the gap is less tolerated and oral cover during the catch-up may be necessary.

Plasma level monitoring

Therapeutic drug monitoring for LAIs is not routine in Indian practice and Maudsley does not advocate it for most patients. Three scenarios change this. First, **suspected nonadherence in a patient on Risperdal Consta**: one published series found that 9.5% of plasma samples from patients on RLAI contained no risperidone or 9-hydroxy-risperidone, suggesting missed injections were being recorded as administered. A trough plasma level (drawn just before the next injection) clarifies whether the depot is being delivered. Second, **renal impairment with paliperidone**: dose reduction is required at creatinine clearance below 80 mL/min, and plasma levels confirm therapeutic range during the reduction. Third, **concurrent CYP enzyme inducers or inhibitors with aripiprazole**: strong CYP2D6 or CYP3A4 modulators (rifampicin, carbamazepine, certain antiretrovirals, certain antifungals) shift aripiprazole metabolism enough to warrant dose adjustment, and plasma levels guide the call. For FGA depots, plasma level monitoring is rarely indicated; the wide therapeutic range and the absence of an unambiguous toxicity threshold make levels of limited clinical use.

09 / PROFILE

Choosing by patient profile

Nine clinical archetypes recur in Indian LAI decisions. The choice for each is constrained by the Indian cost ladder, but the pharmacological preferences below are the starting positions before cost is applied. Where cost narrows the field to a single FGA depot, the typical fall-back is named.

1. First-episode psychosis

Goals are to minimise relapse, enhance adherence and avoid long-term EPS and metabolic burden. Maudsley and IPS CPG 2026 both support LAI use in first-episode patients once oral tolerability is established. Preferred: **aripiprazole LAI** (lowest EPS, no prolactin, low metabolic) or **paliperidone PP1M** (well-tolerated, no oral overlap with loading, monthly). Avoid high-potency FGAs in this group (lifetime tardive dyskinesia risk accumulates). Indian fall-back: paliperidone PP1M as Paliris LA where cost permits; flupentixol decanoate at the lower D2 potency end of the FGA tier where cost binds.

2. Documented or covert nonadherence

Goals are to ensure delivery, allow objective monitoring (missed visit equals missed dose), and minimise relapse. Preferred: **paliperidone PP1M** (no oral overlap with loading regimen, monthly, deltoid). Avoid Risperdal Consta in this profile precisely because of its three-week oral cover requirement (the patient who does not take oral risperidone for three weeks after the first injection has, in effect, been started on no medication for three weeks). Indian fall-back: haloperidol decanoate where cost binds; fluphenazine decanoate where cost binds harder.

3. History of extrapyramidal symptoms

Goals: minimise D2 antagonism burden. Preferred: **aripiprazole LAI** (partial D2 agonist, lowest EPS risk of any LAI). Olanzapine pamoate has low EPS risk but PDSS observation is the binding logistic constraint. Avoid: all FGAs, particularly fluphenazine, haloperidol, zuclopenthixol. Indian fall-back: paliperidone PP1M where aripiprazole is unavailable (paliperidone EPS rate is lower than risperidone and substantially lower than any FGA).

4. Prolactin-related side effects

Goals: choose prolactin-sparing options. Maudsley canon (principle 08) is verbatim. Preferred: **aripiprazole LAI** (may even lower prolactin) or **olanzapine pamoate** (neutral). Avoid: risperidone microspheres and paliperidone PP1M (highest prolactin elevation among LAIs). Indian fall-back: switching to oral aripiprazole is the practical default where the LAI form is unavailable.

5. Obesity, metabolic syndrome, diabetes

Goals: minimise weight gain and insulin resistance. Preferred: **aripiprazole LAI** (lowest metabolic). Risperidone LAI is moderate. Avoid: olanzapine pamoate (highest metabolic burden of any LAI). Indian fall-back: haloperidol decanoate has low metabolic risk despite high EPS; the trade-off is movement disorder for cardiometabolic protection.

6. Aggression, repeated relapse, structured supervision needed

Goals: sustained D2 blockade, robust antipsychotic exposure. Preferred: **haloperidol decanoate**, **zuclopenthixol decanoate**, or **flupentixol decanoate** (all strong D2 affinity, all amenable to high-dose long-interval administration). Maudsley's observational edge for zuclopenthixol in time-to-discontinuation may favour it where the long-term aggression risk is dominant. Paliperidone PP1M is acceptable where tolerability is the priority.

7. Need to avoid oral overlap

Goals: establish therapeutic levels quickly, no adherence-dependent oral phase. Preferred: **paliperidone PP1M** (loading regimen achieves therapeutic levels without oral overlap) or **olanzapine pamoate** (onset in 2 to 3 days, no oral required, but PDSS observation mandatory). Avoid: Risperdal Consta (3 weeks oral overlap minimum), aripiprazole Maintena (2 weeks oral overlap), FGA depots (1 to 4 weeks oral overlap).

8. Special populations: pregnancy, elderly, renal impairment

Pregnancy: NICE recommends avoiding depot preparations in women planning pregnancy unless previously responsive to one. Best reproductive safety data among LAIs: haloperidol decanoate (most studied) and aripiprazole LAI (limited data, oral form considered relatively safe). Paliperidone-specific warning: detectable in plasma up to 18 months after a Trevicta dose; the prolonged half-life is the contraindication, not a single property of the molecule. Elderly: start at lowest possible dose, longer intervals; aripiprazole one-injection-start preferred over two-injection-start in over-65s. Renal impairment: paliperidone requires dose reduction in moderate impairment (creatinine clearance 50 to 80 mL/min: 50 mg loading day 1, 25 mg day 8, then 25 to 75 mg monthly). Aripiprazole LAI requires no dose adjustment in renal or hepatic impairment but adjustment with strong CYP2D6 or CYP3A4 modulators.

9. Rural setting, limited healthcare access

Goals: minimise visit frequency, ensure long duration of effect. Preferred: **paliperidone PP3M** where available (it is not, in India). Indian fall-back: flupentixol decanoate or zuclopenthixol decanoate at every-4-week interval; haloperidol decanoate at every-4-week interval. The absence of PP3M and PP6M from the Indian formulary is most clinically costly in this profile, where the patient might most benefit from quarterly or biannual dosing.

10 / BIPOLAR

LAIs in bipolar maintenance

Long-acting injectable antipsychotics in bipolar disorder are a smaller and more specific literature than the schizophrenia evidence base, with three findings that residents should commit to memory. The Maudsley 15th edition reproduces and extends them from the 14th.

The three findings

First, **risperidone LAI and aripiprazole LAI both reduce the risk of recurrence of manic and hypomanic episodes** versus placebo, robustly. The effect size is consistent across published trials of both agents.

Second, **risperidone LAI and aripiprazole LAI have no effect on the risk of depressive recurrence** in bipolar disorder. This is Maudsley canon (principle 12), verbatim. The protection is mood-direction-specific. LAIs prevent the next manic episode; they do not prevent the next depressive episode. A patient with a predominantly depressive course on bipolar maintenance gains less from an LAI than a patient with a predominantly manic course.

Third, **there is no evidence to support the benefit of LAIs over oral antipsychotic treatment in bipolar maintenance.** The Maudsley position is that LAIs in bipolar disorder are an option for adherence-related concerns, not a pharmacologically superior alternative. The 2017 FDA approval of Abilify Maintena for bipolar I maintenance monotherapy, extended in 2023 to Abilify Asimtufii, established aripiprazole LAI as the only LAI formally indicated for bipolar maintenance in regulatory terms.

First-generation LAIs in bipolar disorder

Support is weak. Very limited evidence suggests FGA LAIs may reduce manic recurrence; they do not prevent depression and may worsen it. The clinical implication for Indian practice is that the FGA tier, despite being cheap and available, is a poor fit for bipolar maintenance. A patient with bipolar I and a history of depressive episodes is more likely to do worse on haloperidol decanoate than on no LAI; the depressogenic potential of high-potency D2 blockade is non-trivial.

What this means in Indian bipolar practice

The clinically defensible LAI choices for bipolar maintenance in India narrow to:

- **Aripiprazole monohydrate (Maintena)** as the first choice on pharmacological grounds (FDA-approved indication, no prolactin, no metabolic burden, no depressogenic D2-saturation effect). Constrained by import-only availability.
- **Paliperidone PP1M** as the practical second choice where aripiprazole LAI is unavailable, on the grounds of monthly dosing and tolerability, but with the caveat that the manic-recurrence-only protection still holds.
- **Risperidone microspheres (Consta)** as a third choice in patients previously stable on oral risperidone with predominantly manic course.

The FGA tier is not recommended for bipolar maintenance even where cost otherwise binds the choice. A bipolar patient with both adherence concerns and a binding cost constraint is, in Indian practice, a patient for whom an LAI strategy may not be the right answer; oral mood stabiliser (lithium or valproate) with structured adherence support may be a better fit than a depot antipsychotic with a depressogenic edge.

THE CLINICAL IMPLICATION

An LAI in bipolar disorder is a choice in favour of manic-recurrence protection at the cost of depressive-recurrence neutrality. For the patient with a clear manic-pole-dominant course and adherence concerns, an aripiprazole or paliperidone LAI is reasonable. For the patient with mixed or depressive-pole-dominant course, lithium or valproate with structured adherence is the safer bet. The choice between LAI and oral in bipolar maintenance is not the same as the choice in schizophrenia maintenance, where the LAI advantage is broader.

LAIs alongside lithium and valproate

Bipolar maintenance in Indian practice is mood-stabiliser-led, with an SGA antipsychotic added for adherence, mania-recurrence protection, or persistent psychotic features between episodes. The LAI question therefore usually arises as: "this patient is on lithium 900 mg per day with three breakthrough manic episodes in two years; should we add an LAI?" The Maudsley position is that the LAI is a reasonable adjunct in this scenario, but the mood stabiliser remains the anchor of relapse prevention, particularly against the depressive pole. Lithium plasma monitoring (target 0.6 to 0.8 mmol/L for maintenance), renal function and thyroid function should be tracked at standard intervals regardless of LAI co-prescription. The combination of lithium plus aripiprazole monohydrate LAI is well-tolerated in published series and is the most defensible bipolar-maintenance LAI regimen on current evidence. Lithium plus paliperidone PP1M carries higher prolactin burden; lithium plus Tolaz LA carries higher metabolic burden and requires close glucose and lipid monitoring.

When LAI is not the answer in bipolar

Three bipolar profiles where an LAI is not the right answer. First, the **predominantly depressive course**: LAIs do not protect against depression; adding one to a patient with three depressive and one manic episode over five years offers little against the dominant pole. Second, the **rapid-cycling presentation**: long half-life formulations make dose adjustments slow and limit the clinical responsiveness needed in rapid cycling; lithium plus lamotrigine with structured adherence is often a better fit. Third, the **postpartum or pregnancy-planning patient**: the long half-life of LAIs is precisely what makes them problematic when reproductive considerations change. NICE recommends avoiding LAIs in women planning pregnancy unless there is a clear history of nonadherence and previous LAI response; the paliperidone-specific warning (drug detectable in plasma up to 18 months after Trevicta) is the strongest case in point.

11 / INDIA

The Indian decision frame

Four pieces of Indian-specific infrastructure shape every LAI decision: the Indian Psychiatric Society's 2026 schizophrenia clinical practice guideline, the Mental Healthcare Act 2017's capacity and consent provisions, the National List of Essential Medicines 2022 inclusion or absence, and the cold-chain and trained-staff reality of Tier 2 and Tier 3 city practice.

The IPS CPG 2026 position

The Indian Psychiatric Society's clinical practice guideline for management of schizophrenia, published by Sahoo and colleagues in Indian Journal of Psychiatry in January 2026, reverses the older "last-resort" framing for LAIs.[9] The current IPS position is that LAIs should be offered **proactively after the first relapse or when nonadherence is detected**, not after multiple failed oral trials. The CPG explicitly endorses LAI use in first-episode psychosis where oral tolerability has been established. Recommended agents are tiered: in resource-limited settings, the four FGA depots (haloperidol, fluphenazine, flupentixol, zuclopenthixol decanoate); where SGAs are available, risperidone microspheres, paliperidone palmitate, aripiprazole monohydrate, olanzapine pamoate. The IPS guideline is more aligned with Wei 2022 and Maudsley 15th than the 2010s-era practice it replaces. Indian psychiatric residents trained in the past decade should expect the guideline frame to be tested in their exit examinations from 2026 onward.

The Mental Healthcare Act 2017 capacity rule

The MHCA 2017 does not address LAIs by name. The Act's general framework applies. Three sections matter for LAI prescribing.[11]

Sections 86 to 89 establish that capacity is decision-specific. A patient with capacity may refuse an LAI even if the clinician recommends it. Sustained refusal of an LAI in a patient with capacity cannot be overridden by clinical judgement; it can only be revisited if the patient's capacity changes.

Section 14 permits advance directives. A patient may specify acceptance or refusal of injectable formulations in their advance directive; this binds future treatment unless the patient revokes it with capacity.

Sections 89 and 90 (supported admission of up to 30 days and beyond 30 days) permit treatment over patient objection only if the patient lacks capacity and the nominated representative consents. An LAI under supported admission is permissible but carries high audit risk; documentation of capacity assessment, nominated representative consent, and Mental Health Review Board notification beyond 30 days is mandatory. Unlike emergency ECT (Section 94) and psychosurgery (Section 95), LAIs are not subject to explicit MHCA prohibition, but the same procedural safeguards apply in spirit.

The NLEM 2022 gap

The National List of Essential Medicines 2022, reviewed by Parmar and colleagues from the psychiatric perspective in Indian Journal of Psychological Medicine 2023, lists sixteen psychotropics.[12] Among the LAIs, only **fluphenazine decanoate (injection 25 mg/mL)** is included. Haloperidol injection 5 mg/mL (short-acting) is listed; haloperidol decanoate is not. Risperidone, olanzapine and aripiprazole are listed in oral forms only; none of the SGA LAIs is on NLEM 2022. The clinical implication is that district mental health programme free-drug supply yields oral antipsychotics plus haloperidol short-acting injection plus fluphenazine decanoate, but no other LAI.

The Indian patient who would benefit from paliperidone PP1M at the public-sector level cannot have it through DMHP supply. The Paliris LA generic has reduced the out-of-pocket burden but has not put the molecule on the essential medicines list.

The cold-chain and infrastructure reality

Risperidone microspheres (Consta) require validated cold-chain transport. In Tier 2 and Tier 3 cities, reliable cold-chain availability is limited to large private hospitals and specialty centres. Paliperidone palmitate (PP1M and PP3M) is aqueous suspension and similarly cold-chain dependent, though slightly more tolerant of transport excursion. Oil-based FGA depots (haloperidol, fluphenazine, flupentixol, zuclopenthixol decanoate) tolerate ambient storage and are the LAIs of choice where cold-chain reliability is the binding constraint. Olanzapine pamoate's three-hour post-injection observation requirement is the single largest infrastructural barrier; the staffing model required to deliver this routinely is not present in most Indian outpatient setups.

> *The Indian aporia is not which LAI to prescribe. The pharmacological choice is largely solved. The aporia is which LAI the patient in front of you can afford, can reach, and can receive under conditions that the clinic can deliver. The cost ladder, the cold-chain map, and the NLEM gap together write the prescription before the prescriber does.*
>
> APORIA 02

> THE BOTTOM LINE
>
> LAIs in Indian practice are under-used. The IPS CPG 2026 and Maudsley 15th both support broader and earlier use. The constraints are structural rather than pharmacological: cost (fluphenazine at thirty rupees a month is on a different ladder rung than Consta at eleven thousand), supply (only fluphenazine is on NLEM 2022; everything else is private), cold-chain (limits SGA LAI uptake in Tier 2 and Tier 3 cities), and infrastructure (olanzapine pamoate's PDSS observation requirement effectively excludes it from routine outpatient practice). The Sun Pharma paliperidone generic and Torrent's Tolaz LA have eased the cost dimension. The structural gaps in the formulary (no PP3M, no PP6M, no aripiprazole domestic generic, no Aristada or Asimtufii) cap what Indian practice can offer regardless of psychiatrist intent. The work of the resident on the inpatient call is to make the best decision the local cost ladder and supply realities permit, with the Maudsley 15th edition and IPS CPG 2026 as the canon and the patient's life as the consequence.

A consent script for the OPD

A practical model script for proposing an LAI to a patient and family member during the OPD interview, adapted from MHCA 2017 capacity provisions and informed-consent best practice. The script translates well into Hindi, Kannada and Marathi; the structure is the same regardless of language. Three components: explanation of the rationale, explanation of the trade-offs, and the explicit invitation to refuse.

SAMPLE LAI CONSENT DIALOGUE

Rationale: "Your illness has come back twice in the last two years. Both times it was when you stopped taking the daily tablets. The injection I am suggesting is the same medicine, given once a month or once every two weeks, so you do not have to remember the tablets every day. We use these injections because the evidence is strong that they reduce hospital admissions by about half compared to tablets in patients like you."

Trade-offs: "The injection takes ten minutes to give and you will need to come to the clinic every two weeks or every month. If you have side effects, they can take longer to settle compared to tablets, because the medicine stays in the body for weeks. You will need to come on the date we give you, give or take a few days. There is some discomfort at the injection site for one or two days."

Refusal: "You can refuse this. We have other options: oral medicines, a different injection, or no medicine with risk of relapse. Tell me what concerns you most about this option."

Document the patient's response, the nominated representative's view where relevant, and the basis for capacity assessment in the case sheet. Under MHCA 2017, the patient with capacity has the final say.

When to refer to a tertiary centre

Three LAI decisions warrant tertiary referral rather than initiation at district-level outpatient setups. **Olanzapine pamoate (Tolaz LA) initiation**: the three-hour PDSS observation requirement is the absolute indication for tertiary referral; this should not be initiated at a centre without a monitored injection room with resuscitation capability. **Aripiprazole monohydrate (Maintena)**: import availability and cost considerations align with tertiary or large private-hospital practice, where the supply chain through GNH India or specialty distributors is established. **LAI initiation in pregnancy or postpartum**: the reproductive safety considerations, peripartum coordination with obstetric care, and intensive monitoring requirements all argue for tertiary-centre management. Routine FGA depot maintenance, Paliris LA initiation, and stable patient continuation can be done at district-level psychiatry OPDs with appropriate training and supply.

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Educational note. This clinical-reasoning essay is for clinicians and students. It is educational, not treatment advice for any individual. Care decisions belong with the treating clinician. At Weave, care is led by Dr. Niharika Reddy, Consultant Psychiatrist.

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(Taylor, Barnes and Young; Wiley 2025) with Wei 2022 (JAMA Netw Open) and the IPS CPG 2026 (Sahoo et al.) as supporting authorities. Indian brand and pricing data current to May 2026 from 1mg, Apollo Pharmacy, MedPlus, PharmEasy and IndiaMart institutional listings; verify at point of prescription. Authored at Hubli, May 2026.