

# Availability and Policy Alignment of Oral Hypoglycaemic Agents in India: A Cross-sectional Study

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## ABSTRACT

**Introduction:** “Oral Hypoglycaemic Agents” (OHAs) are central to the pharmacological management of Type 2 Diabetes Mellitus (T2DM). While evidence-based treatment guidelines increasingly recommend newer therapeutic agents, essential medicine lists and public procurement systems may not always reflect evolving evidence, potentially limiting equitable access to optimal diabetes care.

**Aim:** To assess the availability of Research Society for the Study of Diabetes in India (RSSDI) recommended OHAs in national and state public medicine lists in India.

**Materials and Methods:** A cross-sectional study was conducted in Government Medical College, Thiruvananthapuram, Kerala, India between January 2025 and March 2025. All OHAs recommended in the RSSDI clinical practice recommendations 2022 were included. A total of eight guideline-recommended OHA drug classes and 24 individual OHAs were assessed for inclusion in the National List of Essential Medicines 2022 of India (NLEM 2022), availability in the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) catalogue, and presence

in State Essential Drug Lists (EDL) from Kerala, Tamil Nadu, Maharashtra, and Assam. Data were analysed using descriptive statistics.

**Results:** Among the eight guideline-recommended OHA drug classes, 3 (37.5%) were included in the NLEM. State-level analysis of 24 OHAs showed that only 2 (8.3%), metformin and glimepiride, were listed across all four states, while 12 (50%) were not included in any of the reviewed State EDL. Assessment of the PMBJP catalogue showed that 19 of 21 OHAs (90.5%) were available.

**Conclusion:** Substantial gaps exist between the RSSDI guidelines 2022 recommendations and public sector availability of OHAs in India, with marked inter-state variability. In contrast, the Jan Aushadhi scheme demonstrated wider inclusion of recommended OHAs, highlighting its potential role as a complementary access pathway. Strengthening the alignment between clinical guidelines and public procurement policies may support more equitable guideline-concordant diabetes care.

**Keywords:** Drug availability, Formularies as topic, Health policy, Health services accessibility

## INTRODUCTION

Diabetes Mellitus (DM) is a major public health challenge worldwide. A disproportionate share of the disease burden is borne by low and middle-income countries, driven by urbanisation and lifestyle changes [1]. India is home to one of the largest diabetic populations, with disease rates doubling in recent decades. Recent national estimates indicate that over 100 million people are affected, reflecting a substantial increase in disease rates over previous decades [2]. Effective long-term glycaemic control is necessary to prevent complications such as kidney failure, blindness, heart disease, stroke and amputations [3].

The OHAs are the cornerstone of pharmacologic management of T2DM. DM treatment guidelines have considerably evolved in the past decade. Along with older established OHAs, newer drug classes have been added enabling individualised patient centric diabetes management. The primary national clinical practice guidelines for the management of T2DM are published by the Indian Council of Medical Research (ICMR) and the Research Society for the Study of Diabetes in India (RSSDI). ICMR published evidence-based guidelines for screening, diagnosis and management of DM in 2018 [4]. The RSSDI guidelines are published in collaboration with the Endocrine Society of India (ESI) and are widely used by clinicians and are considered to be of high quality by peer reviews. The RSSDI guidelines emphasise a patient-centric approach to pharmacological treatment and lifestyle modifications of DM. The latest RSSDI guidelines were published in 2022 [5].

Access to medicines in the public sector is largely determined in India by inclusion in the NLEM [6], State EDLs, and availability

through government-supported schemes such as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) [7]. Economically vulnerable populations are dependent on the availability of medicines through the public health system, which is subject to fluctuations in procurement and distribution of medicines, often leading them to purchase medicines from private pharmacies or experience treatment delays [8,9]. Moreover, essential medicine lists and procurement lists are often not aligned with evolving clinical evidence or evidence-based recommendations, leading to discrepancies between guideline recommendations and medicines available in the public sector [9,10]. This can result in limiting treatment options for patients, variability in care and challenges in achieving standardised and equitable diabetes management [9,11].

Despite the central role of OHAs in diabetes care, there is little systematic evidence examining the extent to which guideline-recommended OHAs are reflected in national and state essential medicine lists and public sector supply schemes in India [5-7,12-15]. Previous studies have primarily focused either on pricing or on prescription patterns, with little attention to formulary inclusion and procurement frameworks [16-20].

The present study aimed to examine the alignment between RSSDI guidelines 2022 recommended OHAs and their inclusion in the NLEM, availability under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana, and representation in selected State EDLs in India.

The primary objectives of the study were to assess the alignment between RSSDI 2022 guideline-recommended OHAs and their inclusion in the NLEM and to evaluate the availability in the Pradhan Mantri Bhartiya Janaushadhi Pariyojana and representation in

selected State EDLs in India and the secondary objective was to examine inter-state variability in the inclusion of OHAs across selected State EDLs.

## MATERIALS AND METHODS

A cross-sectional study was conducted in Government Medical College, Thiruvananthapuram, Kerala, India, using publicly available secondary data. Data were collected from national policy documents [5-7] and official online databases [12-15] between January 2025 and March 2025. The reference standard was OHAs recommended in the RSSDI Clinical Practice recommendations 2022 [5].

This study used only publicly available secondary data and did not involve human participants, patient records, or identifiable personal information. Therefore, ethics committee approval was not required.

A total of eight RSSDI-recommended OHA drug classes, and 24 individual OHAs were included for analysis.

### Inclusion criteria:

- OHAs explicitly recommended in RSSDI 2022 guidelines for T2DM [5];
- Drugs listed in the NLEM 2022, PMBJP catalogue, or State EDLs [5-7,12-15].

The state EDLs from Kerala, Tamil Nadu, Maharashtra, and Assam were included. States were included only if a current and verifiable EDL was publicly available during the study period (January 2025-March 2025).

### Exclusion criteria:

- Injectable antidiabetic agents;
- Fixed-dose combinations;
- Non pharmacological interventions.

Fixed-dose combinations were excluded to maintain uniformity across policy documents and to enable direct comparison of single-agent oral hypoglycaemic availability, as fixed-dose combinations are variably listed across essential medicine frameworks and differ substantially in composition and dosing. OHAs were grouped according to therapeutic class for analysis.

## Study Procedure

Data were obtained from multiple publicly accessible online sources. Each guideline-recommended OHA was systematically assessed for inclusion in the NLEM (Yes/No), availability in the PMBJP catalogue (Yes/No) and presence in State EDLs of Kerala, Tamil Nadu, Maharashtra, and Assam (Yes/No). Data were extracted into the structured data collection format in Microsoft Excel (Version 16.101). For each hypoglycaemic agent, information on therapeutic class, inclusion in NLEM, state EDLs and availability in PMBJP catalogue was recorded. The data was independently cross-checked against original source documents to ensure accuracy and consistency.

All the 2022 RSSDI clinical practice guidelines recommended agents were treated equally for the purpose of assessing policy inclusion and availability. No weighting or prioritisation of OHAs based on clinical importance or usage was applied.

## STATISTICAL ANALYSIS

Data were analysed using descriptive statistics with Statistical Package for Social Sciences (SPSS) version 16.0. Categorical variables were summarised as frequencies and percentages. State-level availability was expressed as the number of states listing each drug.

## RESULTS

A total of eight OHA drug classes recommended in RSSDI Clinical Practice Recommendations 2022 were identified and included in the

analysis. Among the eight RSSDI Clinical Practice Recommendations 2022-recommended OHA classes, 3 (37.5%) were included in the NLEM [Table/Fig-1]. Metformin and glimepiride, which represent first-line and commonly prescribed agents, were listed in multiple strengths in NLEM.

Drug name	Therapeutic class	Included in NLEM	Remarks
Metformin	Biguanide	Yes	Tablet 500 mg; Tablet 1000 mg; Modified-release tablet 1000 mg
Glimepiride	Sulfonylurea	Yes	Tablet 1 mg; Tablet 2 mg
Repaglinide	Meglitinides	No	–
Pioglitazone	Thiazolidinedione	No	–
Teneligliptin	DPP-4 inhibitor	Yes	Tablet 20 mg
Dapagliflozin	SGLT-2 inhibitor	No	–
Acarbose	α-Glucosidase inhibitors	No	-
Voglibose	α-Glucosidase inhibitors	No	-
Semaglutide	GLP-1 receptor agonist	No	–

**[Table/Fig-1]:** Inclusion of guideline-recommended OHAs in the National List of Essential Medicines (NLEM), India.

Among newer therapeutic classes, teneligliptin, a DPP-4 inhibitor was included, whereas other classes such as SGLT-2 inhibitors, Thiazolidinediones, Meglitinides, α-glucosidase inhibitors, and GLP-1 receptor agonists were not included.

State EDLs from Kerala, Tamil Nadu, Maharashtra, and Assam were reviewed to assess inter-state variability [Table/Fig-2].

Drug name	Kerala	Tamil Nadu	Maharashtra	Assam
Metformin	Yes	Yes	Yes	Yes
Glimepiride	Yes	Yes	Yes	Yes
Glibenclamide	No	Yes	Yes	No
Glipizide	No	Yes	No	No
Gliclazide	Yes	Yes	Yes	No
Repaglinide	No	No	No	No
Saroglitazar	No	No	No	No
Lobeglitazone	No	No	No	No
Pioglitazone	Yes	No	No	No
Teneligliptin	Yes	No	No	No
Linagliptin	No	Yes	No	No
Vildagliptin	No	Yes	Yes	No
Saxagliptin	No	No	No	No
Evogliptin	No	No	No	No
Sitagliptin	No	Yes	No	No
Alogliptin	No	No	No	No
Canagliflozin	No	No	No	No
Dapagliflozin	Yes	Yes	No	No
Empagliflozin	No	No	No	No
Remogliflozin	No	No	No	No
Acarbose	No	No	No	No
Miglitol	No	No	No	No
Voglibose	Yes	No	No	No
Semaglutide	No	No	No	No

**[Table/Fig-2]:** State-wise availability of OHAs across selected EDL.

Of the 24 OHAs evaluated, only 2 (8.3%), metformin and glimepiride, were consistently listed across all four states. Several agents showed inconsistent inclusion across states. Gliclazide was listed in three states, while glibenclamide, vildagliptin, and dapagliflozin were listed in two states each. A limited number of agents, including pioglitazone, teneligliptin, linagliptin, sitagliptin and voglibose, were listed in only one state. Half of the assessed OHAs 12 (50%) was not listed in any of the reviewed State EDLs, highlighting substantial inter-state variability in the availability of diabetes medicines.

Availability under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana was assessed for 21 OHAs [Table/Fig-3].

Drug name	Available in PMBJP	Strengths listed (mg)	Formulation
Metformin	Yes	250, 500; SR 850, 1000	Tablet
Glimepiride	Yes	0.5, 1, 2, 3, 4	Tablet
Repaglinide	Yes	0.5, 1, 2	Tablet
Saroglitazar	Yes	4	Tablet
Lobeglitazone	Yes	0.5	Tablet
Pioglitazone	Yes	15, 30	Tablet
Teneligliptin	Yes	20	Tablet
Linagliptin	Yes	5	Tablet
Vildagliptin	Yes	50	Tablet
Saxagliptin	Yes	5	Tablet
Evogliptin	Yes	5	Tablet
Sitagliptin	Yes	50, 100	Tablet
Alogliptin	Yes	25	Tablet
Canagliflozin	Yes	100	Tablet
Dapagliflozin	Yes	5, 10	Tablet
Empagliflozin	Yes	10	Tablet
Remogliflozin	Yes	100	Tablet
Acarbose	Yes	25, 50	Tablet
Miglitol	No	–	–
Voglibose	Yes	0.2, 0.3	Tablet
Semaglutide	No	–	–

**[Table/Fig-3]:** Availability of OHAs in the Jan Aushadhi (PMBJP) scheme.

Of these, 19 (90.5%) agents were available while two OHAs (miglitol and semaglutide) were not listed in the Jan Aushadhi catalogue. First-line agents such as metformin and glimepiride were available in multiple strengths, including sustained-release formulations for metformin. Notably, several newer drug classes, including dipeptidyl peptidase-4 inhibitors and sodium-glucose cotransporter-2 inhibitors, demonstrated broad representation in the Jan Aushadhi catalogue. In contrast, miglitol and semaglutide were not available at the time of assessment.

When viewed by therapeutic class, older OHAs showed the closest alignment across the NLEM, State EDLs, and the Jan Aushadhi catalogue [Table/Fig-4].

Metformin was universally available, and glimepiride appeared in all four states, while newer or second-line classes were far less consistently included. Although some SGLT-2 and DPP-4 inhibitors were available through Jan Aushadhi, their presence in state lists was limited, and GLP-1 receptor agonists were absent altogether. Overall, established agents remained far more accessible in the public sector than newer treatment options.

## DISCUSSION

The present study showed that older OHAs were consistently represented across national and state essential medicine lists, while

several newer guideline-recommended agents had limited inclusion. Similar patterns have been described in other low- and middle-income settings, where essential medicine frameworks tend to favor long-established, affordable therapies and adopt newer antidiabetic drugs more gradually [21-23]. Studies from countries such as Brazil and South Africa have also reported gaps between diabetes treatment guidelines and medicines available through public-sector formularies [24,25]. These similarities suggest that the misalignment observed in the present analysis likely reflects broader structural features of essential medicine selection rather than isolated national or state-level differences.

Within India, previous policy analyses have likewise noted variability across State EDLs and delays in updating procurement lists in line with evolving diabetes guidelines. The current study builds on this evidence by examining alignment across national, state, and Jan Aushadhi sources together, providing a more integrated view of public-sector availability of OHAs. Biguanides (Metformin) and sulfonylureas (Glibenclamide, Glipizide, Gliclazide, Glimepiride), which are widely used as first-line agents in T2DM were widely included in NLEM as well as state EDLs. These older agents are off-patent and are widely available as generics. They are also subject to price regulation, thus making them favorable from a public procurement and cost-effectiveness perspective. The continued presence of glibenclamide in NLEM and state procurement lists despite its exclusion from contemporary RSSDI recommendations highlights ongoing lag between guideline updates and state-level medicine selection. In contrast, several newer therapeutic classes such as SGLT-2 inhibitors and GLP-1 receptor agonists endorsed in RSSDI guidelines were absent. Essential medicine election frameworks prioritise drugs with strong evidence of population level benefit, long term safety and cost-effectiveness rather than comprehensive therapeutic choice [20-26]. Consequently, essential medicine lists are intentionally more restrictive than clinical guidelines, which include a broader range of treatment options to support individualised care [27].

At the state level, there is considerable variation in inclusion of OHAs. Kerala and Tamil Nadu reflect southern states with comparatively strong public health infrastructure and higher reported diabetes prevalence. Maharashtra represents a large and socio economically diverse state with mixed urban-rural healthcare delivery. Assam represents the northeastern region, which is often underrepresented in health systems research and faces distinct access and logistical challenges [2,28-31]. The older OHAs metformin and sulphonylureas were universally listed in all four state EDLs examined. Half of the assessed OHAs were not listed in any of the state EDLs, reflecting substantial interstate heterogeneity. This shows considerable disparity with the latest evidence-based treatment guidelines and reflects differences in state-level procurement policies. This may be due to either budgetary constraints or a delay in updating EDLs. From a patient perspective, this translates as unequal access to effective diabetes treatment depending on the geographic location [9].

The clinical implications of these gaps must be interpreted in context. For the majority of patients with T2DM, older agents such

Therapeutic class	Example agents (RSSDI 2022)	Line of therapy*	Included in NLEM 2022	Available in PMBJP	Listed in ≥1 State EDL	Listed in all 4 states
Biguanides	Metformin	First-line	Yes	Yes	Yes	Yes
Sulfonylureas	Glimepiride, Gliclazide, Glibenclamide	First/Second line	Yes	Yes	Yes	Yes (Glimepiride)
Meglitinides	Repaglinide	Second-line	No	Yes	No	No
Thiazolidinediones	Pioglitazone	Second-line	No	Yes	Yes (limited)	No
DPP-4 inhibitors	Sitagliptin, Teneligliptin, Linagliptin	Second-line	Yes (Teneligliptin)	Yes	Yes (selected)	No
SGLT-2 inhibitors	Dapagliflozin, Empagliflozin	Second-line (high-risk pts)	No	Yes	Yes (limited)	No
Alpha-glucosidase inhibitors	Voglibose, Acarbose	Second-line	No	Yes	Yes (limited)	No
GLP-1 receptor agonists	Semaglutide	Second-line (high-risk pts)	No	No	No	No

**[Table/Fig-4]:** Class-wise representation of OHAs across public sector medicine lists.

\*Line of therapy based on RSSDI Clinical Practice Recommendations 2022.

as metformin and sulfonylureas remain clinically effective and are the backbone of treatment. However, newer drug classes offer additional benefits for specific patient subgroups such as those with cardiovascular disease, heart failure or chronic kidney disease [32-34]. Restricting these agents in the public sector may therefore disproportionately affect these higher-risk patients who stand to benefit from these newer OHA classes and limit the opportunities for evidence-based personalised care [35].

In contrast to the national and state EDLs, the Jan Aushadhi scheme demonstrated a broader inclusivity of the latest RSSDI guideline-recommended drugs. Newer therapeutic classes of OHAs were available in multiple strengths. This demonstrates the potential of the Jan Aushadhi scheme to serve as a complementary mechanism to drug access in locations where the state-level EDL procurement lists are limited. But availability through Jan Aushadhi does not automatically translate into equitable access, as geographic distribution of outlets, prescribing practices and patient awareness also play a role in real-world utilisation [36].

Central to essential medicine selection is cost-effectiveness. Even though newer agents show clinical advantages in selected patients, their higher acquisition costs limits inclusion in publicly funded programs. Phased or targeted inclusion of newer therapies can be facilitated by generating Indian cost-effectiveness evidence and strengthening local health technology assessment processes [37].

Strengthening the coordination between guidelines development bodies, policy makers, and procurement agencies responsible for essential medicine selection could help bridge the gap between evolving clinical recommendations and public-sector medicine availability. Regularly updating state-level EDLs based on the latest evidence-based guidelines, integration of cost-effectiveness considerations, and greater coordination between states is the need of the hour. This will ensure equitable and guideline-concordant diabetes care across the states within India's public health system.

The strength of present study lies in its use of publicly available and authoritative data bases rather than proprietary data sets which ensures a transparent and reproducible assessment.

### Limitation(s)

However, the study is limited by its reliance exclusively on secondary data sources and thus on document availability and not on actual medicine procurement or supply or utilisation at public health facilities. Patient level prescribing patterns or treatment outcomes which might be important determinants of real-world access, were not assessed. Despite these limitations, the use of transparent and reproducible data strengthens the policy relevance of these findings.

### CONCLUSION(S)

The present study demonstrates a substantial mismatch between RSSDI guideline recommendations and their availability within public sector medicine lists in India. There are pronounced gaps between national and state procurement levels of essential medicines despite broader coverage under the Jan Aushadhi scheme. Older agents such as metformin and sulfonylureas were consistently represented across lists, while several newer guideline-recommended agents showed limited or absent inclusion, with considerable variation between states. Overall, these findings highlight incomplete alignment between clinical recommendations and public sector medicine availability in India.

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**PLAGIARISM CHECKING METHODS:** [Jan H et al.]

- Plagiarism X-checker: Jan 14, 2026
- Manual Googling: Feb 26, 2026
- iThenticate Software: Feb 28, 2026 (2%)

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