Oregon Prescription Drug
Affordability Board

Insulin Data Process

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Document History

Version	Date	Description	Author
v01		Original draft	PDAB Staff

Overview

The following methodology was used to develop the preliminary list for insulin drugs for the 2025 Oregon Prescription Drug Affordability Board (PDAB) affordability review. The data used to produce the list is from the calendar year 2023.

Data Sources

1. **APAC Database**- "The Oregon All Payer All Claims Database (APAC) is a large database that houses administrative health care data for Oregon's insured populations. In particular, APAC includes medical and pharmacy claims, non-claims payment summaries, member enrollment data, billed premium information, and provider information for Oregonians who receive coverage through commercial insurers as well as through public payers such as Medicaid and Medicare."[1] The APAC Database is maintained by the Oregon Health Authority (OHA) and was the source of the 2023 pharmacy claim data for these outputs. Medical claims were not utilized for these lists. APAC information is gross and not net of rebate.

2. **Centers for Medicare & Medicaid Services** – (CMS) The "Selected Drug List" for the Medicare Drug Price Negotiation was used as a resource to verify if an insulin drug was present or absent from the current drug price negotiation list.[2]

3. **Federal Drug Administration** – (FDA) The administration is part of the U.S. Department of Health and Human Services. Information published by the FDA was used to gather information relevant to NDC values of interest for insulin.[3]

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[1] https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx; See also https://www.oregon.gov/oha/HPA/ANALYTICS/APAC%20Page%20Docs/APAC-Overview.pdf

[2] https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

[3] https://open.fda.gov/data/ndc/; See also https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory; See also https://dps.fda.gov/ndc; See also Search Orphan Drug Designations and Approvals

4. **Medi-Span** – This Wolters Kluwer drug database was the primary source for NDC information.[4]

5. **Contracted Clinician** – This resource provided assistance and validation for, insulin therapeutic class level (Medi-Span classification), naming conventions, insulin subclass categorization, and the presence and number of therapeutic alternatives.

6. **National Institute of Health, National Library of Medicine** – (NIH) The NIH was used as a secondary source for NDC information throughout the process.[5]

Assumptions and Constraints

1. Data provided or acquired by all listed sources is true, accurate, and as complete as possible.

2. Due to confidentiality constraints and data use agreements, the analysis outputs must be deidentified and in aggregated form. No individual claim data can be represented.

3. The APAC Database "does not include data on uninsured individuals or other populations who pay out-of-pocket for their health care; nor does it include data on individuals insured through certain federal programs such as Tricare, the Federal Employees Health Benefits Program, the Indian Health Service, or the Department of Veterans Affairs. The database also does not collect data on members of small commercial health plans with fewer than 5,000 covered lives. The database does not include information on other types of insurance, such as workers' compensation or stand-alone dental or vision coverage. Additionally, claims related to alcohol and drug treatment are also masked in APAC."[6]

Process – Preliminary Aggregated Insulin Data

1. **Request and received data from the APAC Database from OHA**
    a. A formal request was submitted to OHA for the release of the 2023 data based on specified fields of interest.
    b. The 2023 APAC data was received from OHA. Main data files are in text (.txt) format.
    c. Analytic software was used to read the text files for further analysis.

[4] https://www.wolterskluwer.com/en/solutions/medi-span/medi-span/drug-pricing-data
[5] https://www.dailymed.nlm.nih.gov/dailymed/index.cfm
[6] APAC-FAQ.pdf

2. **Insulin NDC values**
    a. Medi-span was used to identify all active insulin NDC values and their associated data within the database. The Medi-span therapeutic class level of GPI04 for "Insulin" was used to filter NDC values relevant to insulin based on clinician direction.
    b. Any information that could not be identified for specific insulin NDCs via Medi-span was researched across additional resources (see Data Sources, page 3) and added to the insulin NDC list.
    c. Due to the variety of sources used to gather information pertaining to insulin NDCs, standardization was required for analysis. This included using a uniform format for numbers and text so that the analysis software was able to recognize like and differing values. No data values were altered in this process.
    d. Medi-Span naming convention was used for proprietary names. A summarized naming convention was used for the non-proprietary naming and is denoted with an (*) next to the column name in the Excel workbook.

3. **Identification of insulin related claims**
    a. Using analytic software, the resulting NDC list was queried against the APAC pharmacy data to extract all claims associated with the NDC values.
        i. Not all active insulin NDC values from Medi-span were represented in the APAC pharmacy data (no matching claim data for a given NDC).
        ii. NDCs that were not represented in the APAC pharmacy data were removed from the insulin NDC list.
    b. The result of the query in 3(a) above represents the raw data for 2023 for APAC pharmacy claims for insulin.
        i. The APAC database contains some claims that have no associated unique person. This was validated with the Oregon Health Authority.
        ii. The abovementioned value is important to accurately calculate values related to an individual (e.g. amount paid per patient). Those claims with no identifiable unique person were removed from the dataset to avoid skewing the calculations.

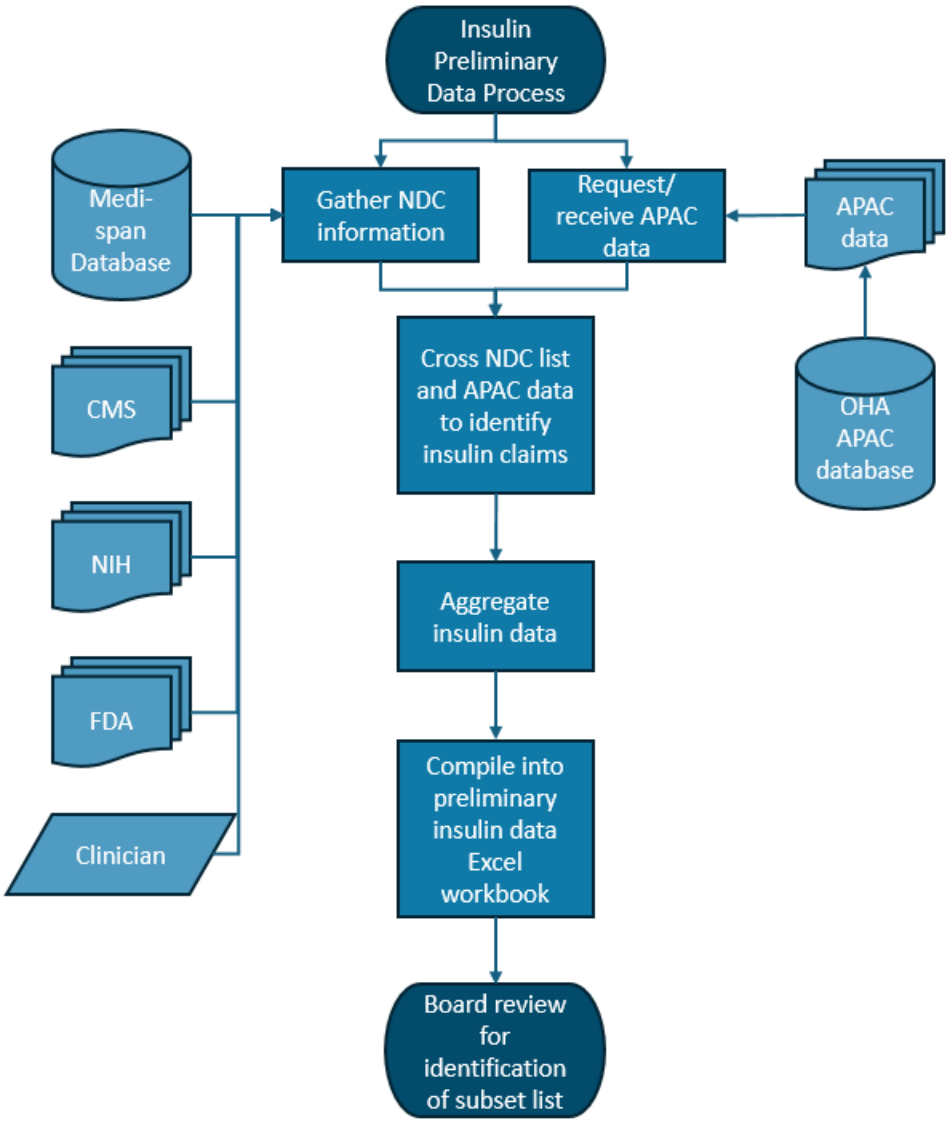
4. **Aggregation of insulin data**
    a. Using the raw data produced in section 3, a programming code was created to select claim data from the raw file for aggregation.
    b. Mathematical functions were used to calculate sums and averages of the values represented. (See Calculations Section)
    c. The resulting information was exported to an Excel workbook with multiple tabs representing the functional aggregated data for insulin.

d. The data was represented from differing parameters (or pivots) including data by NDC, proprietary name, non-proprietary name, and insulin subclass.
    i. Note: A unique individual can be represented more than once based on the parameter of analysis. For example, an individual who is prescribed more than one insulin drug that spans more than one insulin subclass, would be represented more than once in the "data by insulin subclass" tab in the Excel workbook. This can happen with any parameter of aggregation.
    ii. The number of claims is fixed and does not change throughout the data regardless of the parameter of analysis (proprietary name, insulin subclass, etc.).

5. Spreadsheet tabs

a. The Excel workbook, generated in step 4c, was formatted for aesthetics.
    i. Additional tabs were created for a cover page, document history, notes, definitions, and sources for continuity of information.
    ii. Links were created from the cover page to each related page within the Excel workbook.
b. Workbook tabs are as follows:
    i. Cover
    ii. Document history
    iii. Notes
    iv. Definitions
    v. Sources
    vi. NDC Information
    vii. Data by NDC
    viii. Data by Proprietary Name
    ix. Data by Non-Proprietary Name
    x. Data by Insulin Subclass

Figure 1 - Insulin Preliminary Data Process Overview



Calculations

The below calculations were performed to create the insulin lists for 2023. The tab representing the location of where each calculated value can be found in the Excel workbook is denoted in parentheses next to the name of the calculation. Fields in the Excel workbook that are not represented below are not calculated measures.

1. **Percent Change in WAC** (NDC information tab) – End of year package (or unit) price minus the beginning of year package (or unit) price the result of which is divided by the beginning of year package (or unit) price. This value is formatted as a percentage.

2. **Average Percent Change in WAC Over 7 Years** (NDC Information tab)- This calculation is an average of the year over year percentage change in WAC. From each year, over 7 years (1/1/2017 – 12/31/2023), the percentage change is calculated for each year. Next, all percentages are averaged to arrive at the average percent change in WAC over 7 years. This value is formatted as a percentage.

3. **Number of WAC Changes Over 7 Years** (NDC Information tab) – This value is a sum of the number of changes identified in Medi-span for a given NDC over 7 years (1/1/2017 – 12/31/2023). This field is numeric.

4. **Total Payer Paid** (All data tabs) – This is the sum of all payer paid amounts based on a particular parameter (e.g. NDC, proprietary name, etc.). This value is formatted as currency in U.S. dollars.

5. **Total Patient Paid** (All data tabs) – This sum represents all patient paid amounts based on a particular parameter. This includes patient copay, deductible, and coinsurance amounts. This value is formatted as currency in U.S. dollars.

6. **Overall Spend** – (All data tabs) – This calculated value is the sum of the Total Payer Paid and the Total Patient Paid amounts for a specific parameter of interest. This value is formatted as currency in U.S. dollars.

7. **Payer Paid per Patient** (All data tabs) – This value is calculated by dividing the Total Payer Paid amount by the Total Unique Patients. This value is formatted as currency in U.S. dollars.

8. **Paid per Patient** (All data tabs) – This value is calculated by dividing the Total Patient Paid amount by the Total Unique Patients. This value is formatted as currency in U.S. dollars.

9. **Payer Paid per Prescription** (All data tabs) – This value is calculated by dividing the Total Payer Paid amount by the Total Prescriptions Filled. This value is formatted as currency in U.S. dollars.

10. **Patient Paid per Prescription** (All data tabs) – This value is calculated by dividing the Total Patient Paid amount by the Total Prescriptions Filled. This value is formatted as currency in U.S. dollars.

11. **Total Prescriptions Filled** – The total prescriptions for a given parameter (e.g. NDC) based on the claim identifier in the APAC database.

12. **Total Unique Patients** – The unique person (or patient) is based upon the "uniquepersonID" APAC field and identifies a person by identifying them with a unique identifier. "Total Unique Patients" is a sum of all unique patients based on a specific parameter (e.g. NDC). For example, all uniquely identifiable patients related to an NDC are counted once for that NDC. More than one claim can exist for that patient for that NDC but the unique person is counted only once. [7]

Definitions

1. **Bioequivalence** – "Bioequivalence is, in pertinent part: the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."[8]

2. **Biosimilar** - "A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA – the original biologic (also called the reference product). Biosimilars also have no clinically meaningful differences from the reference product. This means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would the reference product. Biosimilars are made from the same types of sources (e.g., living cells or microorganisms) and are just as safe and effective as their reference products."[9]

3. **Brand Name Drug** – A drug sold by a drug company under a specific name or trademark and that is protected by a patent.[10] Brand name drugs may be available by prescription or over the counter.

4. **Generic Drug** - A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.[11]

[7] https://www.oregon.gov/oha/HPA/ANALYTICS/APAC%20Page%20Docs/APAC-Data-User-Guide.pdf
[8] https://www.fda.gov/media/160054/
[9] https://www.fda.gov/drugs/biosimilars/
[10] Drugs@FDA Glossary of Terms | FDA
[11] Generic Drugs: Questions & Answers | FDA

5. **Insulin mix** - A combination of insulin products with a duration of up to 24 hours. Typically given twice daily before meals.[12]
6. **Intermediate Acting (NPH) Insulin** - Human insulin with an onset of about 90 minutes and a duration of up to 24 hours. Typically given once or twice daily.[13]
7. **Long Acting Insulin** - Human insulin analog with a duration of ~24 hours (up to 42 hours with insulin degludec). Typically given once daily.[14]
8. **National Drug Code (NDC)** – This code is a unique identifier for drug products.[15]
9. **Non-proprietary name** – The chemical name for a drug.[16]
10. **Orphan designation** – A drug designated by the FDA as a treatment for a rare disease and when the drug has been granted exclusive marketing rights for a seven-year period to treat rare diseases.[17]
11. **Patient (aka enrollee)** - Individual enrolled for coverage under a health benefit plan.[18]
12. **Payer (aka carrier)** - Any person or entity that provides health benefit plans in the state that include but are not limited to licensed insurance companies, health care service contractors, health maintenance organizations, and any other corporation responsible for the payment of benefits or provisions of services.[19]
13. **Pharmaceutical equivalence** - Drug products that have "identical dosage form and route(s) of administration; contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates."[20]

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[12] Provided by the Contracted Clinician
[13] Ibid.
[14] Ibid.
[15] https://open.fda.gov/data/ndc/
[16] https://medical-dictionary.thefreedictionary.com/nonproprietary+name
[17] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions
[18] https://oregon.public.law/statutes/ors_743b.005
[19] Ibid.
[20] https://www.fda.gov/media/160054

14. **Priority review** – Priority review status for a drug application indicates that the FDA will review the drug within 6 months (at a faster rate than the 10 month standard review).[21]
15. **Proprietary name** – "The protected brand name or trademark, registered with the U.S. Patent Office, under which a manufacturer markets its product. It is written with a capital initial letter and is often further distinguished by a superscript R in a circle (®)." [22] The Medi-span designated proprietary name was used throughout this analysis.
16. **Rapid Acting Insulin** - Prandial human insulin analogs with an onset of 10 to 30 minutes and duration of 3 to 5 hours. Given with meals.[23]
17. **Short-acting insulin** - Regular human insulin with an onset of about 30 minutes. Longer time to onset and longer duration (~8 hours) than rapid-acting.[24]
18. **Therapeutic alternative** - A "drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose."[25]
19. **Therapeutic equivalence** - "The scientific and regulatory foundation for the evaluation of therapeutic equivalence of prescription drug products involves pharmaceutical equivalence, bioequivalence, and the same clinical effect and safety profile for the conditions of use specified in the labeling."[26]
20. **Total prescription filled** - The total prescriptions for a given parameter (e.g. NDC) based on the claim identifier in the APAC database.
21. **Total Unique Patients** - The unique person (or patient) is based upon the "uniquepersonID" APAC field and identifies a person by identifying them with a unique identifier. "Total Unique Patients" is a sum of all unique patients based on a specific parameter (e.g. NDC). For example, all uniquely identifiable patients related to an NDC are counted once for that NDC. More than one claim can exist for that patient for that NDC but the unique person is counted only once.

[21] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review
[22] https://medical-dictionary.thefreedictionary.com/proprietary+name
[23] Provided by the Contracted Clinician
[24] Provided by the Contracted Clinician
[25] PDAB Administrative Rule 925-200-0020
[26] www.FDA.gov

22. **Wholesale Acquisition Cost (WAC)** - The price paid by a wholesaler to purchase drugs from a supplier, typically the manufacturer.[27]

Tools

1. **Microsoft Excel** - This tool is the industry leading spreadsheet software program, data visualization and analysis tool.

2. **RStudio** – RStudio is programming software used to import, clean, organize, query, and analyze data that comes from a variety of sources, including insurance carriers. R has the versatility to process large amounts of data and read the multiple file formats that are encountered in the prescription drug affordability program enabling flexibility in data modeling.

3. **SQL** – (Structured Query Language) – SQL is a standardized programming language used for searching, manipulating, and combining data from relational databases. SQL enables efficiency in retrieving and analyzing data as well as generating reports to inform business decisions.

Conclusion

This document is a living document and will be updated as needed as the affordability review process progresses. The above information is pertinent to the development of the preliminary insulin list. Additional processes will be required for the subset list once the drugs listed for review are selected

[27] https://prescriptionanalytics.com/white-paper/key-terms-in-pharmaceutical-government-pricing/