# KTP AI Project

# Variables for Automated Collection

# NICE Data

Sources: <https://www.nice.org.uk/guidance/published?ngt=Technology%20appraisal%20guidance&ndt=Guidance>

Overall example TA page [Overview | Polatuzumab vedotin in combination for untreated diffuse large B-cell lymphoma | Guidance | NICE](https://www.nice.org.uk/guidance/ta874)

(Other examples will be in sources column if needed)

|  |  |  |  |
| --- | --- | --- | --- |
| Variable | Notes | Source | “Human” Decision needed? |
| TA number  (TA, HST, MTG, HTE) | Example “TA874” | Published NICE guidance (see example TA page) | No |
| Molecule | Also known as “INN” | Published NICE guidance (see example TA page) | No |
| Indication | Example “Polatuzumab vedotin in combination for untreated diffuse large B-cell lymphoma” | Published NICE guidance (see example TA page) | No |
| Reappraisal (Or Appeal) | True or False | Published NICE guidance (see example TA page) à Under History tab -> Appeal Documents or 1 and 2 on guidance documents | This decision is based on the history evidence tab, if there are multiple guidance and review dates etc we usually see it as a reappraisal e.g. “Draft Guidance 2”.  If it is an appeal there will clearly be documents named with “Appeal” in the title |
| End of life (EoL) | True or False | Published NICE guidance (see example TA page) à Guidance à 3 Committee Discussion (very visible) | Yes, If EOL is mentioned then it will likely be true **unless** the company applied for EOL and got rejected. But highly likely it will be EOL |
| Severity Modifier | True or False | Published NICE guidance (see example TA page) à Guidance à 3 Committee Discussion (visible, will have severity in contents at top) | Yes, If severity modifier mentioned then it will likely be true **unless** the company applied for severity modifier and got rejected. |
| Severity Weighting | If yes, which level of QALY weighting: 1.2 or 1.5 or 1.7 | Published NICE guidance (see example TA page) à Guidance à 3 Committee Discussion | This is a number extracted from the text, it will always be mentioned if there is a severity modifier |
| Cancer | True or False | Published NICE guidance (see example TA page) (from indication or therapy code) | Yes but simple word association. This is from the therapy code if one has been assigned.  We could use associated words for this field, such as anything to do with myeloma, unresectable etc in the indication. |
| NICE Appraisal Type | If an appraisal has a TA number (e.g., TA861), then usually “STA” (Single Technology Appraisal” unless multiple medicines evaluated then MTA (Multiple Technology Appraisal). If appraisal is under HST (Highly Specialised Technology) | Published NICE guidance (see example TA page)  (usually STA) | No (STA for Tas, HST for HSTs, simple scraping should be fine here).  Expanding to HTE and MTG |
| NICE first ACD committee papers | Date shown on Appraisal consultation document (ACD).  If no ACD, then use Final Appraisal Document (FAD).  If HST appraisal, use Evaluation Consultation. | Published NICE guidance (see example TA page) à Under History tab | Partially, (Date is visible on page, just need to make sure to get the right one) |
| NICE Decision date | Date shown “Published: DD Month YYYY” next to TA number | Published NICE guidance (see example TA page) (true for terminated appraisals also) | No |
| Outcome | Recommended *(Example: Vutrisiran is recommended, within its marketing authorisation, as an option for treating hereditary transthyretin-related amyloidosis in adults with stage 1 or stage 2 polyneuropathy.)*  Optimised (*Example: Fenfluramine is recommended as an add‑on to other antiseizure medicines for treating seizures associated with Dravet syndrome in people aged 2 years and older, only if:*   * *seizures have not been controlled after trying 2 or more antiseizure medicines* * *the frequency of convulsive seizures is checked every 6 months, and fenfluramine is stopped if it has not fallen by at least 30% compared with the 6 months before starting treatment)*   Recommended (*Example:* | Published NICE guidance (see example TA page) Guidance –> Recommendations  List of not recommended and recommended are in the medicines tracker | Yes decision needed, recommendations would be simpler to analyse, they will have no bullet points under them and say something along the lines of “within it's marketing authorisation”.  Optimisations (or Restrictions) are usually when there are bullet points below the recommendation but we’ve found a few to not really be an optimisation or restriction so some subjective judgement is needed. We can discuss this further.  **Note there are 4 options:**  **Recommended**  **Optimised**  **Not Recommended**  **Terminated** |
| Carer QALYs | Whether Carer QALYs have been taken into account on a decision or not (dummy variable) | Committee Discussion  [Overview | Risdiplam for treating spinal muscular atrophy | Guidance | NICE](https://www.nice.org.uk/guidance/ta755)  Will mention carers, in the example this is under clinical need and utility values | Partially. Any mention of carer will likely mean carers are include but this is not definite.  As shown in the TA, carer is mentioned in clinical need and utility values |
| Real World Evidence | Whether NICE has considered submitted RWE when making their decision (dummy variable) | IQVIA has articles on which TAs have incorporated RWE but no NICE indication for this on the surface  (Example: TA725) | Likely not possible except a deep dive into the evidence document |
| Costs outside the health sector | Whether the models submitted present non-reference-case analyses including benefits and costs (or cost savings) to the government outside of the NHS and PSSA deviation from the reference case | Committee Discussion (Likely)  Evidence  (Likely) | (Being Investigated) |
| Productivity Costs | Does non-reference case analyses include evidence on productivity gains? (If societal perspective accepted then likely) | Committee Discussion (Likely)  Evidence  (Likely) | (Being Investigated) |
| Proportional Approach | Has NICE taken a proportional approach to the evaluation of this TA?  [Taking a proportionate approach to technology appraisals | What we do | About | NICE](https://www.nice.org.uk/about/what-we-do/proportionate-approach-to-technology-appraisals) | (Being Investigated, preliminary thoughts are that this is TAs without a committee discussion but no confirmation) | Not yet definite when proportional approach has been taken. |
| Digital Technology or Med Tech Device | Is the technology a digital technology or device? | TA main page, likely to be HTE and MTG evaluations. | No  Digital technologies are under HTE evaluations so the TA type (which is very clear) would determine a dummy variable  Med Tech Devices are under MTG evaluations. |
| Discounting | Do the models deviate from the current NICE reference case discount rate? | Committee Discussion likely (being investigated) | (Being Investigated) |
| Early Value Assessment for Med-Tech | Is the TA being granted license conditionally using the early value assessment for new technologies implemented by NICE | (Being Investigated) | (Being Investigated) |
| Plausible ICER | The ICER defined as "the most plausible” by the Committee in the guidance document | Committee discussion  [Overview | Risdiplam for treating spinal muscular atrophy | Guidance | NICE](https://www.nice.org.uk/guidance/ta755)  Will be reported explicitly if the company has not deemed it sensitive information in which case it will be discussed in relation thresholds | Partially, If reported it is simple web scraping for any text that has a number xxxx/QALY  If not reported text has to be interpreted to approximate its general magnitude (whether under 30,000 or over 50,000) |
| Product indication approved based on a single arm-trial | The product-indication under appraisal was approved by the regulator based on results of a single-arm phase 3 trial | Evidence Document  (Likely) | (Being Investigated) |
| Price of drug/device | Costs are always presented in the recommendation section at the end | Recommendations | No |
| Combination Therapy | Recommendation, or even the title, will have “with” in its title | Title or Recommendation | No AI needed, simple text association |

# EMA Data

Sources: [Committee for Medicinal Products for Human Use (CHMP) | European Medicines Agency (europa.eu)](https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp)

EMA technology appraisals are all under the CHMP category, they have monthly meetings and publish meeting highlights for these meetings, we get our data from here and the individual medicine pages they have on their site (called EPARs

Further information can be found by clicking on the link under “More information” e.g., “Elfabrio: Pending EC decision”

Graphical user interface, text, application

Description automatically generated

Add a new row/entry for each “**Positive recommendations on new medicines**” and “**Positive recommendations on extensions of indications**”

EMA Variables to collect:

|  |  |  |  |
| --- | --- | --- | --- |
| Variable | Notes | Source | Decision needed? |
| Therapy class | ATC code: first 3 digits, e.g., L01 or N06 | From “More information/Pending EC decision” page | No |
| Product name | Also known as Brand name | From “Meeting Highlights” main page | No |
| INN | Also known as ‘molecule’ | From “Meeting Highlights” main page | No |
| Initial Approval | Initial approval if “Positive recommendations on new medicines”  Extension if “Positive recommendations on extensions of indications” | From “Meeting Highlights” main page | Partial (but an if statement should do here I would think) |
| Indication | Full indication  If minor extension/change to existing indication, e.g., approved for paediatric, then note as “Change to existing indication – [*insert change*]” | From “More information/Pending EC decision” page | Extracting the text is fine here for initial authorisations.  For extensions, need to decide if the new indication is an extension of an existing or an additional indication and put this at the start currently, But we may work out a different way for this project, it does not have to follow the medicines tracker guide fully |
| Cancer | True if therapy class = L01 & L02 | From “More information/Pending EC decision” page | Some classes can be missing but usually this should be scrapable |
| Marketing authorisation holder |  | From “More information/Pending EC decision” page | No |
| CHMP Opinion Date | Noted under “Key facts” – but is the same for each month (use last date in the period of the CHMP meeting period) | From “More information/Pending EC decision” page or use last date in CHMP meeting | No |
| Decision date | Will not be available until a few months after CHMP decision | From medicine’s “EPAR” page | No |
| Orphan indication | If orphan designation will be linked at bottom of “Pending EC decision” or cross-check with diagram in “Meeting highlights page”. Often found under “Authorisation Details” very easily in the EPAR. | From “More information/Pending EC decision” page  OR “Authorisation details” in EPAR webpage. | No, if anything resembling “orphan” is present, it is an orphan drug |
| Therapy area | VLOOKUP formula pulls from Column F | Excel formula | No |
| ROUTE and subroutes | Check NICE website first, search molecule name and see if any appraisals “in development” that match the indication | NICE guidance website | Always “NICE” basically |
| Initial Authorisation/ Extension | If only one indication in the EPAR, then “Initial authorisation”  If more than one indication, then “Extension” | EMA website à molecule EPAR à “Procedural steps taken and scientific information after authorisation” PDF | Yes, Need to count the number of indications or if it is a change of an existing |
| Orphan | True or False  Same process as EMA tab – check if orphan designation | EMA website à From medicine’s “EPAR” page  (very visible) | No |
| EMA date | If “Initial authorisation” then date can be found in “Authorisation details” table on EPAR webpage.  If “Extension” then, go to “Procedural steps” PDF and Ctrl+F “Extension” or keywords from the relevant indication. Add date from 2nd column i.e., “Commission Decision Issued/amended on” | EMA website à molecule EPAR à “Procedural steps taken and scientific information after authorisation” PDF  (Find extension of indication using Ctrl+f) | No if initial authorisation  Yes is extension, often need to go into the pdf, make sure to read the extension of the drug carefully to match NICE’s indication and use the correct date of the corresponding row |