**Pharmacy and Therapeutics (P&T) Committee**

**Medication Use Evaluation (MUE) for Biosimilars Preparation Step-by-Step**

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| --- | --- |
| **Biosimilar name:** |  |
| **Reference Product name:** |  |
| **AHFS Therapeutic class:** |  |
| **Manufacturer:** |  |
| **Date of review/approval by P&T:** | dd/mm/yyyy |
| **P&T conditions/criteria for use** |  |
| **P&T service restrictions (inpatient/outpatient/specific services/etc.)** |  |
| **Date MUE to be presented at P&T:** | dd/mm/yyyy |
| **MUE prepared by:** | first and last name, PharmD, etc. |
| **Preparer Email:** |  |
| **Preparer phone number:** |  |

1. **Background**

* Brief background on disease/clinical issues
* Brief overview of agents used to treat
* Describe any guideline that includes use of agent / place in therapy per guidelines
* Biosimilar agent under review (generic and brand name)
* Date of FDA approval and approved indication(s)
* Usual dosing
* Does biosimilar have black box warning?
* Is there a REMS for this biosimilar?
* Specific insurance concerns (if none, state this):

1. **Product information**

* How supplied:
* Usual dose per day/week/treatment cycle (use whichever is most relevant):
* Considerations for ordering. For example, is a special contract needed?

1. **Methods**

* Review period (start and end dates)
* How patients were identified:
* Data elements captured during chart review (check all that apply):
  + Diagnosis
  + Service
  + Location of administration (inpatient vs infusion center vs office)
  + Dose / Administration issues
  + Relevant side effects (especially side effects related to Black Box warning, serious side effects. No need to include non-serious side effects unless important to the clinical service)
  + parameters suggested by service/pharmacist on service
  + issues with administration? (e.g. infusion time)
  + Safety issues?
  + Order set concerns/issues (is order set being followed or are changes being made during prescribing?)
  + Other outcomes (please specify)
* Describe any other sources used for clinical data review:

1. **Results**

* Total number of patients
* Total number of doses
* Dosing – describe as flat or weight-based dosing as appropriate for the product
  + Min, max, mean, SD, median of doses/dosage per patient (if relevant)
* Present results in table format with % of patients or doses that met criteria
* Results reviewed with member of relevant clinical service

|  |  |  |
| --- | --- | --- |
|  | **Criteria** | **Results (n and % that met criteria)** |
| Criteria | Criterion 1 Diagnosis | n (\_\_\_%) |
| Criterion 2 Ordering service |  |
| Criterion 3 Location of administration |  |
| Etc – list each criterion individually |  |

**Circumstances where criteria were not met**

* Exceptions/Outliers
* Comments on exceptions/outliers
* How discrepancies/exceptions are defined/evaluated (be as explicit as possible)

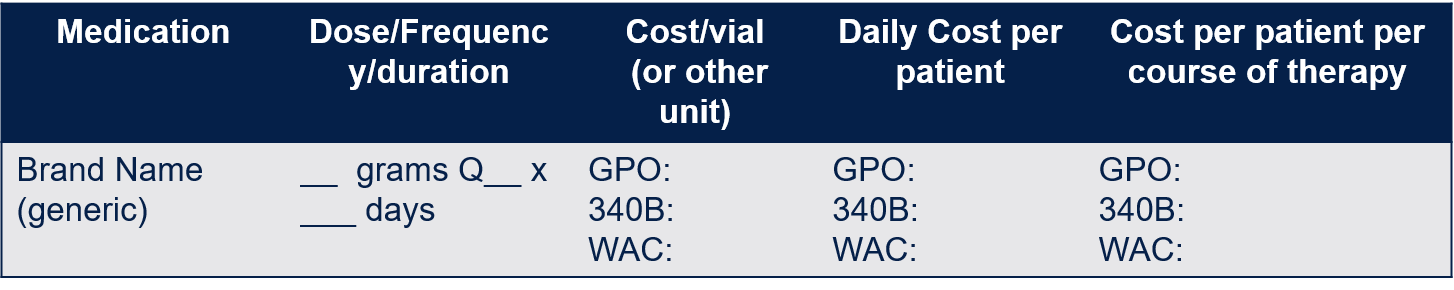
**Data collection limitations**

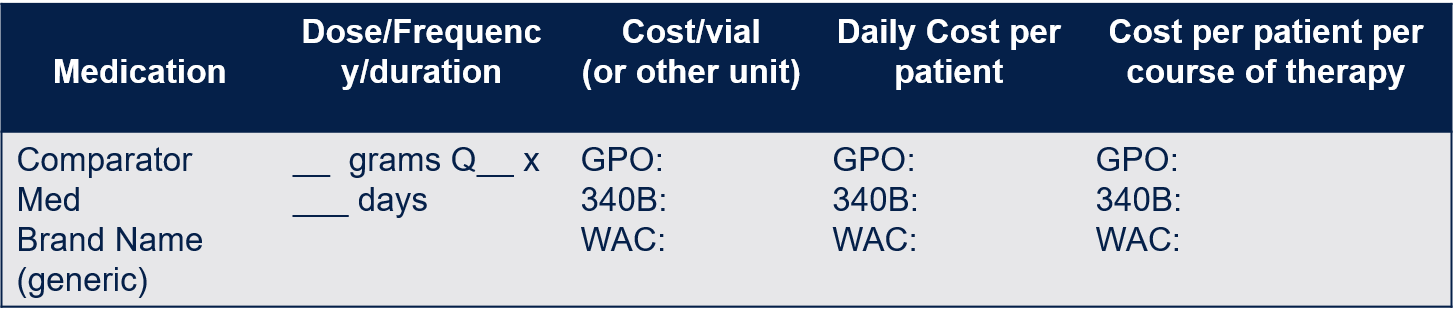
Describe any limitations faced and any solutions proposed or put into place.

1. **Cost**

Please round all costs to nearest dollar amount. You can use the table below (or something similar) to report findings. Please assure the following information is included:

* Cost per unit (tablet, vial, etc) (based on purchasing cost)
  + outpatient (340B)
  + inpatient (GPO/WAC)
* Cost per usual dose and/or usual treatment course (relevant timeframe)
  + outpatient (340B)
  + inpatient (GPO/WAC)
* Observed cost per year based on utilization
  + outpatient
  + inpatient
* Any additional cost due to adverse events, additional medications/ treatment/ device needed
  + pre-medications, testing needing prior to treatment (EKG, etc)
  + unanticipated hospitalization, ED visit, etc?
  + extended time in infusion center?
  + meds/intervention needed to manage adverse reaction?
* Did cost change during the review period?





**Forecasted vs. Actual Utilization and cost**

* Please round to nearest dollar. You may consider the table below, or something like it to summarize the following:
* Forecasted vs actual utilization
* Forecasted vs actual cost and reimbursement
* Use, Cost of alternative treatments
* If a shift in product use was anticipated, how much shift has been observed?
* Potential Alternatives (if none, state there are none)

- Any new alternative(s)/ therapeutic interchange(s) that became approved/ available

- Is the alternative available on formulary? Are providers using the alternative(s)?

- Could the alternative(s) be used instead?

- What is the cost of the alternative(s)?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Estimated cost per patient per course of therapy** | **Estimated**  **annual cost (n=\_\_\_)** | **Actual cost per course of therapy** | **Actual**  **annual cost (n=\_\_\_)** |
| **Medication** | **GPO:**  **340B:**  **WAC:** | **GPO:**  **340B:**  **WAC:** | **GPO:**  **340B:**  **WAC:** | **GPO:**  **340B:**  **WAC:** |
| **Comparator Medication** | **GPO:**  **340B:**  **WAC:** | **GPO:**  **340B:**  **WAC:** | **GPO:**  **340B:**  **WAC:** | **GPO:**  **340B:**  **WAC:** |

1. **Summary**

In a few sentences, summarize main points: drug, disease, purpose of MUE, and key findings.

1. **Recommendation(s)**

* Recommended status on formulary
  + Maintain on formulary, restriction changes, etc
* Recommended changes to prescribing/dispensing workflow
* Plans for re-assessment or follow-up MUE, if appropriate
  + Outcome plan to carry out in follow up

**References**

Please list all references using AMA