# Appendices

* Appendix A: Sample Unsolicited Request Letter
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## Appendix A: Sample Unsolicited Request Letter

Date

Medical Information/Medical Communications Department

Name of Company

Address

Address

Dear…:

[Organization name] has adopted the Academy of Managed Care Pharmacy’s (AMCP) *Format for Formulary Submissions* detailing the process and evidentiary requirements for the provision of clinical and economic information to support formulary consideration. Please consider this letter as an unsolicited request for an AMCP *Format*-based dossier for your product [Name of Product or Products here]. Per the AMCP *Format* the dossier should contain all available medical, economic and other scientific information (including any unpublished and/or off-label study data that are to be considered by our organization) and pharmacoeconomic modeling on all comparator products that we consider for formulary inclusion or as part of therapeutic class reviews.

In addition, we request that you provide, for a period of 6 months, any new published or unpublished information on labeled or unlabeled uses that is specific to the information requested herein that may serve to further inform our decisions on the use of this product.

We consider this unsolicited request to represent the desired information to accompany a formulary submission. Manufacturers should submit a complete dossier well before they expect the product to be considered for formulary review. Our goal is to enable all of the [Organization name] Pharmacy & Therapeutics (P&T) Committees to make evidence-based decisions representing good value for money when selecting preferred treatment options. The AMCP *Format* describes a standardized template for pharmaceutical manufacturers to construct and submit a formulary dossier. The dossier is designed to make the product evaluation process in formulary development more complete, evidence-based and rational.

By submitting this request we recognize that confidential information may be provided. We also recognize the need to respect and honor commercial-in-confidence information and may be willing to sign necessary confidentiality agreements under agreed circumstances.

If you require additional information, please call ………

Sincerely,

## Appendix B: Formulary Monograph Template

**Individual Drug Review**

**Generic Name: [Name]**

**Brand Name: [Name]**

**Manufacturer:** [Text]

**Date of Review:** Month Year

**Reason for Review:** [Text].

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**Abbreviations used in this monograph:**

|  |  |
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**EXECUTIVE SUMMARY**

**Key Questions/Issues and Results of Investigation:**

***Issue 1: What is the evidence of efficacy from clinical trials?***

 [Text. The answers to key questions should normally be no more than a paragraph of modest length. If no evidence was found to answer a particular question, state “No evidence found.”]

***Issue 2: Is there sufficient evidence to assess real world comparative effectiveness?***

[Text]

***Issue 3: What is the evidence of safety?***

[Text].

***Issue 4: What is the value proposition for this product?***

[Text].

***Issue 5: Are there identifiable patient subgroups in which this treatment will be most cost-effective?***

[Text]

**RECOMMENDATIONS TO THE COMMITTEE**

[Summary of findings, key issues & conclusions, 1 or 2 short paragraphs that explain the logic leading to your recommendations.]

Therefore, the following P&T action is recommended:

**ISSUE 1: What is the evidence of efficacy from clinical trials?**

[Narrative summary of evidence for efficacy.]

**ISSUE 2: Is there sufficient evidence to assess real world comparative effectiveness?**

[Narrative summary of evidence for comparative effectiveness.]

**ISSUE 3: What is the evidence of safety?**

[Narrative summary of evidence for safety.]

**ISSUE 4: What is the value proposition for this product?**

**Summary of Product Value**

[Text summary statement]

**Incremental Cost-effectiveness:**

[Discussion of cost-effectiveness analyses]

**Table . Summary of incremental cost-effectiveness ratios found by studies included in this review.**

|  |
| --- |
| **Cost/QALY (USD)** |
| **Reference** |  |  |  |  |  |
| **Setting or Disease 1** |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Setting or Disease 2** |  |  |  |  |  |
|  |  |  |  |  |
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**ISSUE 5: Are there identifiable patient subgroups in which this treatment will be most cost-effective?**

[Discussion of patient subgroups and the evidence that would indicate improved ICER for them. Include a description of relevant biomarkers or other companion diagnostics that would be used to identify these target populations, and the feasibility of using these markers in routine clinical practice.]

**Table . Clinical evidence summary**

| **Ref. and****Evidence Grade** | **Drug Regimens** | **n** | **Time** | **Demographics** | **Design\*** | **End Points/Results/Comments** | **NNT** |
| --- | --- | --- | --- | --- | --- | --- | --- |
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| Abbreviations used in this table: AC =active control, CCS = case-control study, DB = double blind, PC = placebo control, PCS = prospective cohort study, PG = parallel group, MA = meta-analysis MC = multicenter, RCS = retrospective cohort study, RCT = randomized controlled trial, XO = crossover |

**Table . Validation of instruments used in studies included in this review.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Instrument** | **Abbreviation** | **Description** | **Numerical Scale** | **Interpretation of Values** | **M.I.D.\*** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| \* M.I.D. = minimal important difference, usually determined by the originator or owner of the instrument. This number represents a threshold below which a numerical difference is not considered to be clinically meaningful, even if statistically significant. Differences less than this amount are usually excluded from discussions of incremental clinical effect. |

**Table . Cost-effectiveness evidence summary (Reviewers may change this table format to better fit the economic study methodology)**

| **Ref. and****Sponsor**  | **QHES Score** | **Study Design and Treatments Compared**  | **Time Horizon and Demographics** | **Model Inputs and Data Sources** | **Results:** **Base Case, Sensitivity Analysis and Limitations** |
| --- | --- | --- | --- | --- | --- |
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|  |  |  |  |  |  |
| Abbreviations used in this table: LYS = life-years saved, QALY = quality-adjusted life-year, QOL = quality of life. |

**BACKGROUND INFORMATION**

**DISEASE BACKGROUND**

 [Text]

**Disease Burden**

 [Text]

**Pathophysiology**

 [Text]

**TREATMENT ALTERNATIVES**

 [Discussion of other existing pharmacologic alternatives or nonpharmacologic treatments that could be used in place of the drug being reviewed. If there are no existing treatment modalities, indicate “best supportive care” etc. and delete the next two sub-sections.]

**Preferred Existing Therapy**

 [Discuss current treatment standards. If there is a “gold standard” treatment that is endorsed by practice guidelines or specialty society opinion statements, reference these authorities.]

**Other Therapeutic Alternatives**

 [Discuss other generally accepted treatment options, including ‘watchful waiting” or “best supportive care” if these are considered appropriate. ]

**PRODUCT BACKGROUND**

**Pharmacology**

 [Brief description of mechanism. If it is a novel mechanism, a longer description may be appropriate.]

**Pharmacokinetics**

 [Text summary, if kinetics will factor significantly into the decision.]

|  |  |
| --- | --- |
| **Route of Administration:** |  |
| **Bioavailability:** |  |
| **Time to Peak:** |  |
| **Multiple dosing:** |   |
| **Clearance:** |  |

**Adverse Effect Profile**

 [Brief text summary of known side effects and general tolerability from the package insert or other available sources. If clinically important, include a brief table of side effects from the package insert, listing only side effects with incidence rates significantly different from placebo.

This section is for discussion of routine side effects. Major safety issues should be discussed under Issue 3 above.]

**Drug Interactions**

[Text. List these from the package insert. Include a table if appropriate.]

**METHODOLOGY OF THIS REVIEW**

**DATABASES SEARCHED:**

 Medline

 Embase

 Cochrane Controlled Trials Registry

 Clinicaltrials.gov

 Other: [Name]

**SECONDARY SOURCES:**

 Cochrane Reviews Database

 BCBSA TEC

 NICE

 Other: [Name]

**SEARCH STRATEGY:**

 [text]

**INCLUSION CRITERIA:**

 [text]

**Search Results:**

|  |  |
| --- | --- |
| **Study Type** | **N** |
| Randomized controlled trials (RCT) |  |
| Meta-analyses of RCTs |  |
| Systematic reviews |  |
| Randomized pragmatic Trials |  |
| Prospective cohort studies |  |
| Retrospective cohort or case-control studies |  |
| Economic modeling studies |  |
| Case Series |  |
| RCT abstracts, not peer-reviewed |  |
| Other abstracts, posters, etc., not peer-reviewed |  |

**Articles Excluded from Evidence Synthesis:**

|  |  |
| --- | --- |
| **Reason for Exclusion** | **N** |
|  |  |
|  |  |
|  |  |

**REVIEW PREPARED BY**

**[Author’s Name(s), degrees and organization]**

**REFERENCES**