Adhering to Multiple Guidelines for Preparation of Formulary Submission Dossiers: Aligning With Payer Expectations

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Workshop Presenters

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 - Chief Pharmacy Officer







Agenda

- Overview of US formulary submission guidelines
 - Academy of Managed Care Pharmacy (AMCP)
 Format (version 2.1, April 2005)
 - WellPoint HTA Guidelines (version 1.1, September 2008)
 - RegenceRx Medication Value Appraisal Principles (March 2009)
- Payer perspectives
- Industry and consultant agency perspectives







Product Information

Type of Evidence	AMCP Format	WellPoint HTA Guidelines	RegenceRx Value Appraisal Principles
Product Description and Label	✓	\checkmark	\checkmark
FDA-approved and Other Indications	\checkmark	\checkmark	\checkmark
Future Indications Anticipated		\checkmark	\checkmark
National Drug Code (NDC)	\checkmark		\checkmark
Average Wholesale Price (AWP)	\checkmark	\checkmark	\checkmark
Wholesale Acquisition Cost (WAC)	\checkmark		\checkmark
AHFS Classification	\checkmark		✓
Pharmacology and Pharmacokinetics	\checkmark	\checkmark	\checkmark
Contraindications, Warnings/ Precautions, Adverse Events, Interactions	✓	✓	✓
Dosing and Administration	\checkmark	\checkmark	\checkmark
Access and Supply	\checkmark	\checkmark	\checkmark
Length of Course of Treatment		\checkmark	\checkmark
Market Share Information	\checkmark	\checkmark	\checkmark
Coprescribed/Concomitant Therapies	\checkmark		\checkmark
Concise Comparison With Comparators	\checkmark	\checkmark	\checkmark
Patent Life Expectancy		\checkmark	\checkmark







Disease Information

Type of Evidence	AMCP Format	WellPoint HTA Guidelines	RegenceRx Value Appraisal Principles
Epidemiology	✓	\checkmark	✓
Risk Factors	\checkmark	\checkmark	✓
Pathophysiology	\checkmark	\checkmark	✓
Clinical Presentation	\checkmark	\checkmark	\checkmark
Economic Burden	\checkmark	\checkmark	✓
Societal or Quality-of-Life Burden	\checkmark	\checkmark	✓
Characteristics of Target Population		\checkmark	
Number of Target Population in Plan		\checkmark	
Characteristics of Subpopulations		\checkmark	







Treatment Patterns

Type of Evidence	AMCP Format	WellPoint HTA Guidelines	RegenceRx Value Appraisal Principles
Treatment Pathways	\checkmark	\checkmark	\checkmark
Therapy Interventions by Disease Stage		\checkmark	✓
Common Treatment Options	\checkmark	\checkmark	✓
Place of Product in Therapy	\checkmark	\checkmark	✓
Disease Management Strategies	\checkmark		✓
Relevant Treatment Guidelines	\checkmark	\checkmark	✓
Critical Appraisal of Treatment Guidelines		√ *	√ *
Expected Outcomes of Therapy	\checkmark		✓
Comparator Therapies and Doses	\checkmark	✓	\checkmark
Adherence/Persistence to Therapies		✓	✓

 $[\]checkmark^*$ Indicates that this section is particularly important in the review process.







Clinical Evidence

Type of Evidence	AMCP Format	WellPoint HTA Guidelines	RegenceRx Value Appraisal Principles
Clinical Descriptions of Comparators	\checkmark	\checkmark	\checkmark
Clinical Study Summaries for Comparators		\checkmark	✓
Clinical Analysis of Comparators		\checkmark	✓
Clinical Study Summaries for Product	\checkmark	\checkmark	\checkmark
Summaries of Systematic Reviews/ Meta-analyses for Product	✓	✓	✓
Outcome Claims for Product	\checkmark	\checkmark	✓
Product Statement of Clinical Advantage	\checkmark	✓	✓
Generalizability	\checkmark	\checkmark	✓
Grading of Clinical Evidence		√ *	√ *
Pharmacovigilance		\checkmark	✓

 $[\]checkmark^*$ Indicates that this section is particularly important in the review process.







Economic Evidence

Type of Evidence	AMCP Format	WellPoint HTA Guidelines	RegenceRx Value Appraisal Principles
Health Economic Study Summaries for Comparators		✓	✓
Health Outcome Studies for Comparators		\checkmark	\checkmark
Cost-effectiveness Analysis of Product	\checkmark	✓	\checkmark
Budget Impact Model for Product	\checkmark	\checkmark	\checkmark







Health Plan - Focus/Emphasis

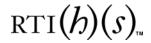
AMCP Format	WellPoint HTA Guidelines	RegenceRx Value Appraisal Principles
Clinical Evaluations	Emphasizes critical appraisal of primary (RCTs) and secondary studies (systematic reviews/meta-analyses) and practice guidelines to determine relative clinical value, then links these findings to modeled cost-effectiveness	Emphasizes critical appraisal of literature, systematic reviews, meta-analysis, and treatment guidelines; applies principles defined by BlueCross BlueShield Association Technology Evaluation Center (BCBSA TEC), Consolidated Standards for Reporting Trials (CONSORT), and The Delfini Group, LLC. for overall value analysis
Outcomes	Emphasizes patient-oriented outcomes, including quality of life, productivity outcomes, and real-world/effectiveness data	Emphasizes net heath outcomes that are clinically relevant and scientifically validated
Modeling	Encourages use of valid predictive models for new reviews, but prefers models utilizing real- world claims for re-reviews	Emphasizes models that are built on foundation of well-designed clinical studies to support model assumptions and applicability to plan
Budget Impact	Encourages use of detailed total cost impacts (pharmacy, medical, and total cost)	Encourages evaluation of total cost impacts (pharmacy, medical) and net cost impact
Claims	Emphasizes that all claims be empirically evaluable	Emphasizes all claims be reported and expressed in a transparent manner
Monitoring and Verification	Recommends that all claims be monitored, verified, and reported annually over a 3-year timeframe	Monitors claims on an annual basis for changes in trends, evolving science, and utilization patterns

Note: AMCP, WellPoint, and RegenceRx are not the only guidelines used by health plans for formulary decision-making.









Evidence -- Critical Appraisal DelfiniTM Validity & Usability Grading Scale

Wellpoint RegenceRx

Grade A: Useful – The evidence is strong and appears sufficient to use in making health care decisions; it is both valid and useful.

Grade B: Possibly Useful - The evidence is potentially strong and might be sufficient to use in making health care decisions.

Grade B-U: Possible to uncertain usefulness -The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty. **Grade "High to Low B": Possibly Useful** - The evidence is potentially strong and might be sufficient to use in making health care decisions.

•High B: Evidence is strong enough to conclude that results are probably valid and useful; however, study results from multiple studies are inconsistent, or studies may have some (but not lethal) threats to validity.

Low B: Evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that evidence cannot fully reach a high Grade B, and uncertainty is not great enough to fully warrant a Grade U.

Grade U: Uncertain – There is sufficient uncertainty so that caution is urged regarding the use of the information in making health care decisions.

Grade UV: Uncertain Validity - perceived methodological weaknesses

Grade UU: Uncertain Usefulness – methodology appropriate but applicability of results uncertain

Grade UVU: Uncertain Validity and Usefulness – combination of the above

Grade UA: Uncertainty of Author – author uncertain about findings

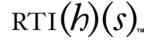
Grade X: Not Useful - studies are so poorly done and are so potentially misleading that the strongest caution is urged about their quality

Grade U and X evidence is not considered by P&T Committee.









Industry and Consultant Perspectives

- Identify key internal stakeholders early to facilitate establishment of realistic timelines
- Understand your plans and familiarize yourself with their review cycles
- Use a single multifunctional team to prepare all dossiers in support of a product
 - Internal team only or in collaboration with a consultant agency
- Plan ahead to facilitate using the same text for parallel sections in different dossiers
- Remain flexible!







References and Links

AMCP

- Academy of Managed Care Pharmacy (AMCP). Format for Formulary Submissions, Version 2.1: A Format for Submission of Clinical and Economic Data in Support of Formulary Consideration by Health Care Systems in the United States. April 2005.
- Available at: http://www.fmcpnet.org/data/resource/Format~Version_2_1~Final_Final.pdf

WellPoint

- WellPoint. Health Technology Assessment Guidelines: Drug Submission Guidelines for New Products, New Indications, and New Formulations, Version 1.1. September 2008.
- WellPoint. Health Technology Assessment Guidelines: Drug Submission Guidelines for Re-Evaluation of Products, Indications, and Formulations, Version 1.1. September 2008.
- Available at: https://www.wellpointnextrx.com/wps/portal/wpo/client/formulary/providerpharmacytheraputics

RegenceRx

- Regence. Formulary Submission Guidelines (ADM 11). March 2009.
 - AMCP Format for Formulary Submission, version 2.1
 - Manufacturer Request for Dossier and Product Material
- Regence Medical/Medication Policy Development and Review Process
 - http://blue.regence.com/policy/medication/introduction.html
 - http://blue.regence.com/trgmedpol/intro/

Other links

- BlueCross BlueShield Association. Technology Evaluation Center.
 http://www.bcbs.com/blueresources/tec/tec-criteria.html
- Consolidated Standards for Reporting Trials (CONSORT). http://www.consort-statement.org/
- The Delfini Group, LLC. <u>www.delfini.org</u>







