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Case Studies on the Local Coverage Process*

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1. Introduction

As providers, beneficiaries, device manufacturers, and other stakeholders strive to more fully understand the working parameters of the Medicare local coverage process, there is considerable value in presenting a more global, integrated approach. There are three major defining forces, which provide such a framework, and can be further exemplified by selected recent coverage case studies. These three forces are (1) specific regulatory mandates of the Medicare program, (2) the creation of stakeholder partnerships, and (3) the need to properly use medical evidence. Most coverage policies represent a combination of these forces. In fact, there is only the occasional local coverage scenario, which is characterized by the pure expression of any solitary element.

2. Local and National Coverage Decisions

The provision of services by the Centers for Medicare and Medicaid Services (CMS) to its beneficiaries is predicated on the determination of medical necessity, once a service has a proven benefit category within the statutorily defined parameters of the program. Title XVIII of the Social Security Act, Section 1862 (a)(1)(A)[1] states "No payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Two pathways exist in which ser-

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From: *Clinical Evaluation of Medical Devices: Principles and Case Studies, Second Edition*
Edited by: K. M. Becker and J. J. Whyte © Humana Press Inc., Totowa, NJ

Table 1
Process Comparisons

	LCD	NCD
Requestors	Usually provider-based	Highly diverse
Breadth of services addressed	Variable	Usually narrow
Role of systematic literature reviews	Variable	Critically important
Advisory Committee referral	Mandatory (Carrier Advisory Committees): relatively broad review responsibilities	Elective (Medicare Coverage Advisory Committee): Focus on evidence evaluation
Key milestones and public comment opportunities	Initial draft policy 90-day notice and comment finalize policy	Tracing sheet "announcement" draft decicion memo 30-day notice and comment final decision memo

LCD, local coveage determination; NCD, national coveage ddetermination.

vices may be granted coverage under the Medicare program: (1) local coverage determinations (LCDs), formerly known as local medical review policies, and (2) national coverage determinations (NCDs). The overwhelming majority of decisions are made at the local level. Emerging, often high-impact technologies typically find themselves in the realm of the NCD evaluation process. Although linked by the overriding need to establish medical necessity before coverage may be granted, these processes differ in some fundamental ways, as summarized in Table 1. First and perhaps most importantly, LCD requests for coverage originate largely with Medicare contractor (that is, either Part A fiscal intermediaries or Part B carriers) interactions with provider stakeholders, whereas NCDs can be generated from a much broader base of requestors, including, but not restricted to, manufacturers, beneficiaries, providers, legislators, and even contractors.[2] Because local Medicare contractors tend to partner with local providers, often through local (as well as national) medical societies, requests from manufacturers are often expressed through local providers that have embraced emerging technologies (e.g., drugs, devices) within their practices, and, in turn, contact contractors about coverage.

Second, LCDs are often broad, having been designed to adjudicate claims for a diverse set of services. To illustrate, a physical therapy service's LCD typically might cover multiple restorative modalities, just as an LCD on chemotherapy would address many oncologic indications of salient therapeutic agents. Thus, the core of an LCD is the delineation of medical necessity, which can be translated into *Current Procedural Terminology/International Classification of Diseases*, 9th Revision, Clinical Modification (CPT/ICD-9-CM) code pairings, for the predominately electronic auto-adjudication of claims. Alter-

natively, the scope of an NCD tends to be relatively narrow in that specific diagnostic/therapeutic modalities are thoroughly evaluated through an evaluation of all available peer-reviewed literature, along with other sources (e.g., national specialty society position statements, practice guidelines). Except under limited circumstances, such as the November 2001 rule regarding laboratory NCDs,[3] the NCD process defers the actual formulation of code pairings to local contractors.Third, there is a mandated review[4] of all proposed LCDs by contractor-based Carrier Advisory Committees (CACs). In contrast, at the national level, there is an elective referral of pending requests for either contract technology assessments, via CMS' partnership with the Agency for Health Research and Quality (AHRQ) and/or deliberations by the Medicare Coverage Advisory Committee (MCAC). Thus, such referrals depend on the need for CMS to obtain additional analytical support on specific issues that is above and beyond what can be feasibly generated via internal systematic literature reviews. Whereas the local CAC is constructed mainly to accumulate provider input of varying types, the MCAC is responsible for technical perspectives on the state of the medical evidence, along with consumer and other advocacy viewpoints. Finally, publication formats differ for the LCDs and NCDs. For an LCD, draft policies are posted on contractor Web sites for 90-day review, during which time both general (public) comments are obtained, in tandem with those from CAC representatives. Following this notice-and-comment period, draft LCDs are finalized and then implemented in accordance with local systems specifications, although the term *finalization* is a misnomer because policy updates and revisions can occur at any time providing that stakeholders give sufficient justification for coverage expansion. Referrals through the CAC/comment process are required only under the scenario of possible restricted coverage. In addition, under recent legislative mandates,[5,6] the new LCD format requires the publication of companion documentation, including coding guidelines, which must be separate from the expression of medical necessity language in the LCD itself. Both LCD reconsiderations[7] and appeals[8] may be exercised as additional pathways for policy alteration. During the evaluation period, new NCDs are posted on the CMS Web site via a tracking sheet, and the subsequently published draft Decision Memoranda are subject to a 30-day public comment period. This differs somewhat from the draft LCD counterpart, which is posted at the conclusion of its initial deliberative period. Sixty days after the conclusion of this comment period, a final Decision Memorandum is posted, and implementation instructions are concurrently available. As noted above, certain implementation steps, such as matching payable CPT codes with ICD-9-CM codes are usually reserved for development by local contractors, pursuant to the receipt of such instructions. Any subsequent national policy alterations must occur via a separate formal request for reconsideration[9] or an appeal.[10]

3. Decisions Made At a Contractor Level

Furthermore, in the case of TrailBlazer Health Enterprises, LLC[SM], policy-making at the contractor level, with respect to physician services under Part B, is described by a complex myriad of forces in which resources are accordingly allocated, such that approximately 100 million claims per year can be properly adjudicated within its five jurisdictions (Delaware, District of Columbia, Maryland, Texas and Virginia). Whereas the LCD is a working document designed to enable electronic edits to auto-adjudicate claims via the assignment of limited diagnostic codes[11] to specific procedural codes,[12] many other coverage decisions and related activities occur outside the LCD process described above. Specifically, there is a multidisciplinary group of clinicians and nonclinicians (i.e., the medical policy team) who follow various deliberative pathways on emerging issues (e.g., procedures, devices), which are typically referred from stakeholders (e.g., local providers, industry). Some of the issues the groups consider include:

1. Coding and/or pricing related issue(s) with no coverage action necessary.
2. When an LCD on a service already exists, the issue is whether to expand current coverage (issues regarding contraction of existing coverageneeds to be automatically referred back to the CAC/Web site review process).[13]
3. If no LCD on the service exists, one might be considered via referral to the triannual Selection Meetings in which the medical policy team decides which draft LCDs will be published for comment and review during the next CAC cycle (in the interim, no edits are in place to restrict coverage).
4. There is no pre-existing LCD, and medical policy team opts for noncoverage and informs the requestor(s), who may submit additional information and/or medical evidence when it becomes available.
5. No LCD on the service exists, because the NCD specifications (including any revisions) provide enough local guidance to make an LCD unnecessary.
6. Under rare circumstances, individual patient considerations can be granted via special-need (e.g., compassionate use) situations, which are outside the parameters of the policy-development process.

The policy selection process requires further elaboration because it synthesizes the different priorities as faced by the medical policy team. For example, interjurisdictional contractors such as TrailBlazer have had to consolidate all prior state-specific LCDs into single documents, which now cover all its jurisdictions. To illustrate, during calendar year 2004, TrailBlazer emphasized such consolidation of existing policies, in lieu of new local policy development. As new multistate Medicare Administrative Contractors[14] are created under the Medicare Modernization Act of 2003, this type of policy consolidation will likely become much more visible. Also, data-driven considerations, such as claims volumes, are key determinants of this selection process. Perhaps most

importantly, the process of selecting such LCDs, in tandem with subsequently drafting new policies or redrafting existing policies, reflects the underlying dynamic in local policy formulation, as well as the interplay of regulatory, collaborative and evaluative forces.

Regulatory forces comprise those mandates under which Medicare contractors must craft policy. These are multifaceted and include the Program Integrity Manual and the "National Coverage Determination" publication (100-3) of the Internet Only Manual, Change Requests, and *Federal Register* notices, in tandem with management directives from CMS staff. The appropriate and timely assimilation of such diverse information provides the fundamental backdrop against which all other coverage activities must take place.

Collaborative forces, in the context of Medicare Part B, characterize the relationship that contractors (carriers) develop with their local provider communities, across all their state jurisdictions (parallels can be formulated with respect to fiscal intermediaries and their institutional providers). Although periodic CACs may symbolize the expression of this ongoing partnership, its backbone is the much wider array of local practitioners, who may be requesting new covered services, either independently or in concert with additional stakeholders (e.g., manufacturers). In fact, the Web posting of draft LCDs is ultimately intended for the medical community at large and is not restricted to CAC participants.

3.1. The Role of Evidence-Based Medicine

The evaluative forces modulate the above regulatory and collaborative forces by enabling the "reasonable and necessary" application of covered services to illnesses and injuries that are based on adequately documented support in the published medical literature. Although this paradigm of evidence-based medicine (EBM) cannot always apply to every situation in which LCDs must be made, it remains an overriding theme in this admixture of policy development.

In practice, EBM represents a spectrum of evaluative endeavor, which, in its purest form, involves the systematic search for improved health outcomes resulting from the medical device, drug, or procedure under examination. There is a hierarchy of medical evidence in which certain types of study designs (e.g., randomized controlled trials [RCTs]) are more robust in demonstrating improved outcomes than are less rigorous counterparts, such as epidemiological studies and case series analyses. This systematic review of the published literature on a given service can consequently maximize the opportunity for Medicare contractors to properly evaluate services during policy development.

Relying on EBM presents several practical considerations found at the local level. First, in the event that abundant published literature is available, such complex systematic reviews may be beyond the usual scope of contractor-based

abilities. In such situations, any available systematic reviews (or technology assessments), such as those published by the Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) or other AHRQ-designated evidence-based practice centers, can be extremely helpful.

Second, by way of contrast, there can be the persistent dearth of published evidence, particularly among new devices, which have not undergone extensive trials. Whereas large-scale RCT designs for new drugs often provide benchmarks of adequate rigor, such resource-consuming efforts often may not be feasible in the context of medical devices.

Third, there are frequently inherent shortfalls in the ability of the published literature to demonstrate that diagnostic tests have reasonable and necessary clinical use in that they improve measurable health outcomes. By contrast, median overall survival is a type of health outcome that might be used to assess a new chemotherapeutic agent, thus underscoring this particular relative convenience in considering therapeutic modalities. Although a new diagnostic test may strengthen the ability to detect a particular disease (i.e., test sensitivity), as well as minimize the occurrence of false-positive diagnoses (i.e., test specificity), such studies of test performance[15] are not configured to determine whether patients will ultimately have improved health outcomes. However, one might infer that improved diagnosis can, in pertinent situations, lead to more timely and effective subsequent treatment.

Finally, some types of EBM studies, such as cost-effectiveness or cost-benefit analyses, highlight resource limitation as a potential consideration in formulating coverage decisions, although at the present time, CMS prohibits contractors from basing Medicare reasonable and necessary determinations on cost.

3.2. Understanding the Balance of Factors

Readers should be cautioned that there is not always a clear demarcation between regulatory, evaluative, and collaborative interests. For example, although one might alternatively suggest that EBM could be included within the regulatory component, it is equally reasonable to assert that it should be deemed an independent element, given the historically ill-defined nature of the term *reasonable and necessary*; CMS has not issued specific defining criteria for it.[16] In addition, many clinical specialty societies have developed practice guidelines that may be constructed according to an EBM-type model and/or via input from clinical leaders in the absence of published rigorous evidence to demonstrate improved health outcomes. Thus, if and when contractors use practice guidelines in their coverage deliberations, it might be considered collaborative to the extent that it expresses partnering with the clinical community and evaluative in that many guidelines are crafted according to the principles of EBM.

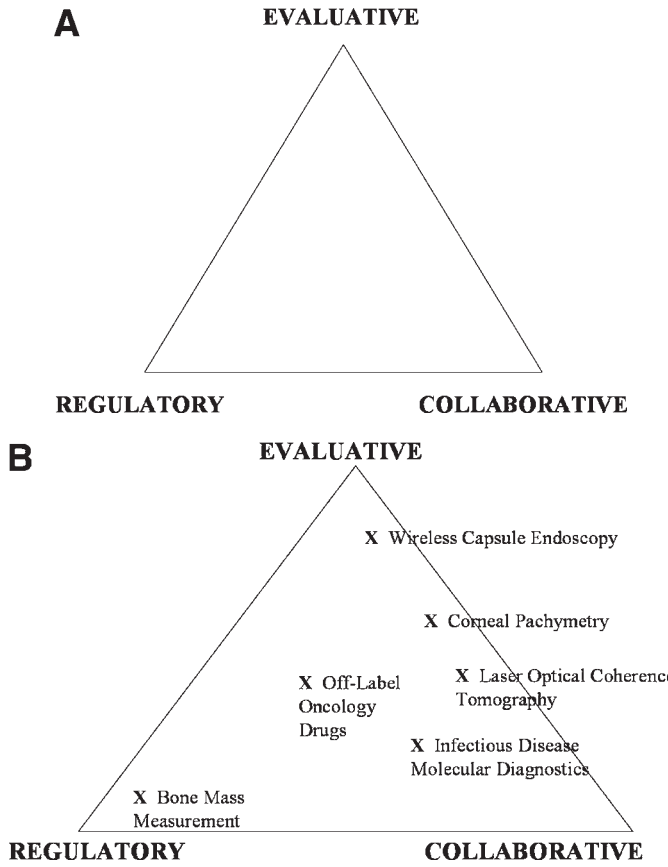

Fig. 1. (**A**) General paradigm of local coverage elements (**B**) using pertinent examples.

Thus, these factors form a triangle (Fig. 1) that is bounded by each of these three metrics. In a theoretical local policy milieu, which is purported to be optimally balanced or symmetrical, one might further suppose that policy is developed in the context of nearly equal regulatory, collaborative, and evaluative components, although this is rarely or ever the case. To illustrate the different configurations of predominate forces, we present some pertinent TrailBlazer medical policy team case studies, which, in turn, enable may help readers circumscribe the policy-development process in both a more informative and more realistic manner.

Four diagnostic device topics followed by a more abbreviated nondevice application referring to off-label coverage of oncology drugs will be presented (Fig. 1B). Although the medical policy team has considered other recent thera-

peutic devices, their didactic value has been somewhat diminished by the combination of limited published literature, in tandem with a relatively narrow spectrum of local provider interest. The case studies are:

4. Case 1: Osteoporosis Screening

The diagnosis of osteoporosis, a disease characterized by low bone mass, and the concomitant determination of fracture risk, has posed a continuing challenge to both radiologists and clinicians.[17] The Balanced Budget Act of 1997 provided the Medicare program with a new osteoporosis screening benefit in which multiple bone mass measurement techniques (e.g., some applied to the skeleton and others to peripheral sites such as the wrist or heel) would be covered within certain frequency parameters if a defined set of beneficiary eligibility criteria were met. In this case, the resultant regulation[18] was sufficiently complex that an LCD[19] was necessary to properly execute the legislation and ensure that appropriate limited coverage was established. Notably, only limited public commentary could be incorporated by the medical policy team, given the instrinsically prescriptive nature of the benefit. For example, during the 2004 statewide consolidation process, multiple clinicians from the different TrailBlazer CACs suggested various clinical indications for which osteoporosis screening would be necessary; however, only ICD-9-CM codes pertaining to the following five qualifying patient categories were permissible: estrogen deficiency, vertebral abnormalities attributable by X-ray to low bone mass, glucocorticoid therapy for at least 3 months, primary hyperparathyroidism, and monitoring for osteoporosis drug therapy. In addition to emphasizing such limitations at each CAC itself, the existing process of including medical policy team responses to all draft LCD recommendations on the published LCD establishes a consistent means for ensuring the transparency of the policy-development process. To respect and maintain the critically important covenant between a contractor and its various stakeholders, commentors are fully entitled to understand decisions regarding whether their suggestions were incorporated into the published LCD.

5. Case 2: Molecular Diagnostics for Infectious Diseases

Molecular diagnostic laboratory testing, which includes DNA and RNA analysis, often provides sensitive, specific, and timely (i.e., relative to conventional methods) identification of diverse biological entities, including microorganisms and tumors. The relevance of obtaining various types of molecular signatures is assuming a prominent role in diagnostic medicine.

Consequently, it is incumbent on the Medicare program to adjudicate claims for such services in a manner that is commensurate with both the clinical and scientific state of the art. Various infectious disease molecular diagnostic assay

platforms, such as nucleic acid amplification testing, are relatively well delineated by the current CPT coding structure. By contrast, the characterization of tumors via gene expression assays is much more complex within the existing CPT framework; therefore, using a set of infectious disease illustrations is more informative.

There are numerous occasions when the need to craft new local policies is a result of previous unmet needs in existing policies. One such example involved the TrailBlazer Non-Covered Services policy,[20] which is a broad compendium of procedural codes pertaining to diagnostic and therapeutic services that have failed to satisfy the requisite degree of medical necessity. For instance, NCD coverage exclusions provide one component of this master list. During release of this revised LCD, as part of the first CAC cycle during calendar year 2003, multiple commentors wrote that many molecular diagnostic codes (e.g., specific to bacteria or viruses) should not have been included on this list. The primary reason for the original inclusion of such codes in the policy was the lack of claims track records; as a result, it was necessary to focus on the potential use of such codes in the future, rather than continuing in the mode of retrospective data analysis, because such diagnostic techniques had been rapidly gaining a foothold in routine patient evaluation and management.

In fact, during the 90-day comment period, a considerable amount of literature, such as letters of support, were received from various stakeholders, including local pathology practices, national specialty and trade organizations, diagnostic test manufacturers, and academic medical centers. After reviewing this material and calling stakeholders, it became abundantly clear to medical directors that the most prudent course of action would be to develop an Infectious Disease Molecular Diagnostic Testing LCD[21] specifically crafted to address these complexities. The current venue of treating such codes in "reverse fashion"—that is, simply continuing to delineate non-coverage only—was deemed unsatisfactory. Thus, this new file served as a substrate for policy development.

The necessary work had only just begun, because a host of individual coverage decisions needed to be made. The CPT manual listed 23 separate microorganisms, and under the pertinent molecular diagnostic codes, each one needed an assay-specific coverage determination. All but one of the microorganisms have three repeating procedural codes, which correspond to the following:

1. Direct probe technique, in which the nucleic acid signature of a suspected microorganism can be detected in a relatively straightforward manner.
2. Nucleic acid amplification testing, which requires that the nucleic acid content be replicated or amplified such that a sufficiently powerful signal can be gener-

ated to detect that micro-organism.
3. Quantitative technique, in which numeric data on nucleic acid content are measured (e.g., "viral load" response may be measured in patients undergoing treatment for human immunodeficiency virus [HIV] infection).

Given that CPT- and ICD-9-CM-limited coverage was specified in the laboratory NCD for both HIV-1 and HIV-2, this left approximately 60 diagnostic categories in which individual coverage determinations would be necessary. Given TrailBlazer's staffing limitations along with the lack of outcomes-based studies on the use of such emerging technologies, the contractor undertook an appropriate pathway of stakeholder collaboration and some degree of evaluation. In addition to reviewing pertinent practice guidelines, when available, and performing some relevant diagnostic tests (i.e., sensitivity and specificity), the contractor placed considerable focus on consultations with expert members of the laboratory community, most notably the Association for Molecular Pathology and the American Society for Microbiology. Furthermore, this partnership enabled the development of a working list of applicable ICD-9-CM codes—corresponding to those clinical presentations associated with current CPT-specified micro-organisms and those not yet listed (e.g., severe acute respiratory syndrome-related coronavirus) that might require molecular diagnostic testing—and allowed claim submission using *not otherwise classified* codes.

This case study illustrates an essential characteristic of the LCD process: its dynamic nature. In this process, a basic underlying assumption is that medical policy team will convert information on new specific molecular assay/micro-organism pairings that have become medically necessity into timely upgrades of the policies.

6. Case 3: Ophthalmologic Diagnostic Testing

Two emerging diagnostic techniques in ophthalmology continue to illustrate the model of mixed collaboration and evaluation found in Case 2. Case 3 highlights an instance in which both LCD and non-LCD-based coverage approaches can be equally appropriate.

6.1. Laser Optical Coherence Tomography (LOCT)

LOCT is a noninvasive, noncontact imaging technique that produces high-resolution longitudinal cross-sectional tomographs of ocular structures in real time, consequently facilitating more precise diagnoses. LOCT has been well documented as an imaging diagnosis in the early detection of glaucoma.[22,23] It is also a valuable technique in the evaluation and treatment of patients with retinal disease,[24,25] particularly certain macular abnormalities such as cysts, holes, pseudoholes, and puckering. Before LOCT, more limited tools (i.e., clinical examination and fluorescence angiography) were available to evaluate

such pathologies. Furthermore, LOCT can aid in making surgical management decisions, such as helping to determine the presence of vitreoretinal traction, which may influence the use of laser vs surgical approaches in diabetic macular edema.

During the routine LCD selection process in 2003, the medical policy team weighed the options of combining individual state-specific policies on LOCT and policy retirement, because contractors need to periodically review existing LCDs to determine whether they are achieving their objectives of high-quality adjudication of claims. After consultations with both general ophthalmologists and retinal specialists, the medical policy team decided to consolidate and refine the existing policies to allow this new technology to target appropriate patient populations properly.[26] Although its decision was not driven by RCT data, the medical policy team was quite satisfied that the various emerging applications of LOCT met the threshold of reasonable and necessary.

6.2. Corneal Pachymetry

The ophthalmology community's recent growth in interest in measuring central corneal thickness (CCT) via corneal pachymetry was triggered by two publications in the June 2002 *Archives of Ophthalmology*. Subsequently, the American Academy of Ophthalmology practice guidelines[27] deemed these studies as strong evidence for measuring CCT in the evaluation of primary open-angle glaucoma (POAG). Whereas Kass et al.[28] did not directly address CCT in their RCT, which determined that an ocular hypotensive treatment strategy delayed or prevented the onset of POAG, the companion epidemiological study by Gordon et al.[29] found that CCT was a significant predictive factor in the development of POAG among individuals with elevated intra-ocular pressure.

After TrailBlazer received correspondence during late 2002 and 2003 from various clinicians in its Part B jurisdictions, the medical policy team reviewed these two sentinel studies in tandem with its usual consultations. Although these studies suggested that CCT measurement might not yet be a fully understood, quantifiable entity in the overall risk assessment of glaucoma progression among patients with ocular hypertension, the combination of this evidence, coupled with provider input, ultimately supported positive coverage. When the medical policy team assigned corneal pachymetry a Category I CPT code effective January 2004, it did not implement limited coverage; therefore, no LCD was necessary. As with any new and/or existing physician service, the medical policy team periodically reviews claims data to determine if a future LCD might be warranted. Ultimately, the medical policy team did not consider decision making at the level of specific pachymetry devices. Although there is a common operational principle in the reflection of light or ultrasound from anterior and posterior corneal surfaces, it is not within the regulatory purview of a Medi-

care contractor to evaluate safety and effectiveness; instead, its purpose is to assess the clinical utility of the overall service encompassed by CPT code 76514©.

7. Case 4: Wireless Capsule Endoscopy

The Food and Drug Administration's decision to allow marketing of PillCam™ SB Capsule Endoscopy Given® Diagnostic System (also known as WCE) in August 2001 generated considerable literature on how small bowel pathology could be more optimally visualized. Whereas both upper and lower endoscopy (i.e., colonoscopy) enable evaluation of common disorders of the gastrointestinal system—a region that is relatively less accessible than others—diseases with lower prevalence (e.g., tumors) have been less easily identified, particularly in the absence of upper and lower endoscopic findings. With WCE, the patient digests a small (11×26 mm) capsule that contains a capsule, which generates images and data as it passes through the digestive system, while maintaining normal activities. During the 8-h examination, information from the camera is transmitted to a recorder device worn around the waist. Local providers brought WCE to the attention of the medical policy team, which found it necessary to incorporate this device into its ongoing working agenda.

In February 2003, the BCBSA TEC published a systematic review of the literature. Based on the mandate of the BCBSA TEC's established criteria, the group would need to demonstrate that WCE both "improves the net health outcomes; and … [is] as beneficial as any established alternatives …"[30] to make a favorable decisionon. This technology assessment critiqued three key published studies, involving a total of 72 patients, in which WCE was compared with two alternative modalities, push enteroscopy and a radiographic small bowel barium evaluation. Based on the positive cumulative findings from the appropriately constructed studies, WCE met the BCBSA TEC criteria "in obscure digestive tract bleeding suspected to be of small-bowel origin." This technology assessment was the critical factor in TrailBlazer supporting positive coverage for WCE.

BCBSA TEC's initial finding on WCE did not end the discussion on providing coverage for the procedure. According to the Food and Drug Administration's label,[31] WCE "may be used as a tool in the detection of abnormalities of the small bowel," but whether the technology improved health outcomes (e.g., the ability to both influence and improve patient management decisions based on WCE) regarding indications other than suspected small bowel bleeding had not been determined. Thus, BCBSA TEC published a much more extensive follow-up technology assessment in December 2003,[32] reflecting the burgeoning literature on potential applications such as Crohn's disease.

Similar to its decision on corneal pachymetry (*see* Case 3), the medical policy team has elected to track claims data for this device to later determine whether an LCD might be necessary to better direct reimbursement for WCE.

8. Case 5: Off-Label Oncology Drug Coverage

Although not within the realm of device evaluation, it is reasonable to close this presentation of various case scenarios by posing the question of whether there might be an identifiable paradigm in which all three forces can coexist in fairly even balance. It should be noted that Medicare contractors need to make coverage determinations on non-self-administered chemotherapeutic agents used off-label. Based on CMS directives,[33] decisions must include a substantive evidence-based (evaluative) component. Furthermore, because local oncologists aggressively keep abreast of the research on treatments through reading the latest studies and attending professional society meeting presentations, there exist opportunities for such a convergence of these three elements.

9. Conclusion

In summary, this chapter presents the backdrop under which Medicare carriers are chartered to make LCDs and has provided a triangular paradigm for expressing the regulatory, collaborative, and evaluative boundaries that surround this decision making. Although selected diagnostic devices have been discussed, this model should be extrapolated to the full complement of policy issues. Whereas the more regulatory or prescriptive approach applies to numerous areas, such as podiatry and ambulance services, other issues harmonize greatly with the evaluative WCE approach. In any case, all processes are intended to achieve the endpoint of timely, efficient, and the most clinically appropriate adjudication of Medicare claims.

Acknowledgments

The following individuals from both TrailBlazer Health Enterprises, LLC and its parent company, BlueCross BlueShield of South Carolina, have greatly assisted the author in the preparation of this chapter: Ruth Ledbetter and Kendall Walker, Esq.

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