Avalon Laboratory Benefits Management Program

November 6, 2015
Lab Market

**Clinical laboratory testing is a meaningful challenge for health care**

- Over 4,000 different lab tests exist, and the menu continues to increase in size, complexity, and cost
- Over 9 billion tests are performed each year, more than any other health care procedure
- Lab tests are the basis for at least 70% of clinical decisions
- 30% of volume represents overused or medically unnecessary testing, and not ordering a test when clinically appropriate may reach the same level
- Nearly 3 in 4 physicians say unnecessary tests represent a serious problem
- Over 4 years, the mean number of hours spent teaching medical students about test selection and the interpretation of results is about 10 hours – for many it is less than 5 hours
- Primary care physicians are uncertain about the appropriate test to order in 15% of diagnostic encounters and uncertain about interpretation of results in 8% of cases
  - With 500 million primary care patient visits per year, that means 23 million times a year a primary care physician is uncertain about the appropriate use of a diagnostic test
- Between 15% and 54% of medical errors reported by primary care doctors are related to testing

**High volume, high complexity, and rapid innovation – all are challenges for physicians and payers**

Sources: various studies and Avalon analyses.
The Ripple Effect of Lab Testing

**Spectrum of Influence**

**Avoidance of follow-up care**
- **PSA**: 80% of positive PSA test results are false-positives; one-third of prostate biopsies results in complications; 1% result in hospitalizations; 1 man in 3,000 die prematurely from the related hospitalization
- **Coagulation screening**: PT/PTT is frequently overused pre-op screening test; false positives often result in much more expensive tests (Factor 8 level, Lupus inhibitor testing)
- **PAP**: Abnormalities can result in unnecessary colposcopies, endometrial biopsies and cervicectomies, resulting in $1B+ in avoidable cost annually

**Targeted testing**
- **Chlamydia screening**: Untreated infection of this asymptomatic STI can lead to PID, hospitalization, and is a primary cause of infertility
- **Lipid tests in high-risk populations**: High-risk patients with no lipid profile tests in LTM were 2x more likely to die from cardiovascular disease than those with >2 lipid profiles in LTM
- **BRCA1 testing**: Underutilization of BRCA in select populations
- **HbA1c monitoring**: Insufficient use of HbA1c threshold to identify and manage pre-diabetics and avoid disease progression

**Specialty pharmacy optimization**
- **Colorectal cancer therapeutics**: Cetuximab effective in 20-50% of patients with wild-type KRA gene, 0% of patients with mutated KRAS gene; cost of therapy ~$80K per patient, $450 for diagnostic
- **Effient effectiveness**: Evaluation of patients to identify extensive metabolizers prior to implementation of drug regime (with significant downstream efficiencies through avoidance of ER visits due to ADEs)
- **Cystic fibrosis targeting**: Approval of Vertex pharmaceutical for treatment of CF in patients with specific regulator gene mutation

**Appropriate lab testing improves health care outcomes and affordability**

Avalon Healthcare Solutions – Who we are

• Avalon is a clinical services and information technology company providing comprehensive diagnostic laboratory management services to health plans

• Avalon uses the latest evidence-based medicine to support robust laboratory-related medical policies

• Avalon’s program is a compliant and reliable extension of BlueCross BlueShield of South Carolina’s medical management program

... and what we bring

• Medical Policy - Continuing evaluation of industry developments resulting in creation of new medical policies or revisions to existing policies

• Network - Dedicated to ensuring that patients receive high quality, cost effective laboratory testing

• Analytics - Supported by lab values that enhance member quality of care

• Member Focus – Access to high quality, cost effective laboratory services
Industry Problems

- Rapid escalation of lab test innovation
- Market experiencing increased utilization and costs
- Lab management not primary area of resource and technology deployment
- Industry facing increasing medical and administrative cost challenges

Avalon Solution

- Leading-edge proactive and expert driven lab medical policy development
- Improve access and affordability
- Enhance clinical outcomes and quality
- Complex claims editor to optimize lab test utilization
Medical Management

Avalon medical management represents the leading thinking in the sector with respect to effective lab policy

<table>
<thead>
<tr>
<th>Clinical Advisory Board</th>
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<tbody>
<tr>
<td><strong>Dr. Geoffrey S Baird, MD, PhD – Chair</strong></td>
</tr>
<tr>
<td>Professional Experience:</td>
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<tr>
<td>• Practicing Pathologist</td>
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<tr>
<td>• Director of Clinical Chemistry at Harborview Medical Center, Seattle</td>
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<tr>
<td>• Laboratory Medical Director at Northwest Hospital and Airlift Northwest</td>
</tr>
<tr>
<td>• Associate Professor of Laboratory Medicine and Adjunct Associate Professor of Pathology at the University of Washington</td>
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<tr>
<td>Clinical Interests: Molecular diagnostics, clinical analytics, and rational utilization of lab testing</td>
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<td><strong>Dr. Christopher Tormey, MD</strong></td>
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<tr>
<td>• Assistant Professor of Laboratory Medicine and Molecular Biophysics and Biochemistry at Yale University</td>
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<tr>
<td>• Lecturer in Molecular Biophysics and Biochemistry</td>
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<tr>
<td>• Director of Transfusion Medicine Fellowship</td>
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<td>Clinical Interests: Transfusion medicine</td>
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<tr>
<td><strong>Dr. Timothy Hamill, MD</strong></td>
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<td>Professional Experience:</td>
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<tr>
<td>• Vice Chair, Laboratory Medicine, University of California, San Francisco</td>
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<tr>
<td>• Director, UCSF Clinical Laboratories</td>
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<td>Clinical Interests: Clinical pathology and hematopathology</td>
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<td><strong>Dr. Brian Smith, MD</strong></td>
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<td>• Professor and Chair of Laboratory Medicine; Professor of Biomedical Engineering, Medicine (Hematology), Pediatrics at Yale School of Medicine</td>
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<tr>
<td>• Chief of Laboratories at Yale New Haven Hospital, New Haven, CT</td>
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<td>Clinical Interests: Hematopathology, optimal utilization of state-of-the-art laboratory diagnostics</td>
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Medical Policy

• Evidence-based guidelines for testing across laboratory domain
• Develop reflexive algorithms, used in in-patient setting, for out-patient labs

Reimbursement Policy

• Enables cost containment without adding increased administrative burden
• Automation of policies enables timely lab processing and payment

Avalon Automated Post-Service Claims Editor

• Expedited claims pricing and processing that minimizes disruption to rendering labs
• Prompt adjudication, which minimizes cumbersome procedures like prior authorizations

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Expertise

Execution
Avalon Medical Policy Approach

Avalon supports the development and administration of medical policy to document the applicability for coverage of laboratory testing procedures

• Medical policies provide the foundation for:
  • Medical necessity decision-making process
  • Promoting objectivity and consistency
  • Establishing valid rules-based design to the claims adjudication system

• Avalon’s medical policy administration services:
  • Account for specimen collection and/or processing in the following places of service (POS) locations:
    • Independent Laboratory (POS 81)
    • Outpatient Hospital (POS 22,19)
    • Doctor’s Office (POS 11)
  • Provide for no less than three evidenced-based reference sources, accessed from professional medical societies of the ordering physician, Blue Cross and Blue Shield Association Technology Evaluation Center (TEC), government groups (such as NCCN), and other commercial policy
  • Are current, with scientific references used to support the policy stance being no greater than five (5) years from publication date, with two (2) years preferred
Medical Policy Administration

**Evaluation**
- Clinically-driven evaluation of over 1,200 codes in health plan data
- Top codes routinely account for nearly two thirds of health plan volume
- Apply information from clinical practice trends, peer-reviewed publications, professional society guidelines, etc.

**Policy Creation**
- Created clinical and evidence-based rules for top codes
- Medical policies developed and evaluated with health plan
- Medical policy is the foundation of Avalon’s program and underpins all programs

**Policy Management**
- Claim payment integration with health plan’s claim system
- Evaluate claims against health plan’s laboratory medical policy
- Support and promote provider education initiatives

*Avalon proactively identifies new lab tests and employs repeatable processes to develop evidence-based medical policy and automated claim reviews to enforce that policy*
Prior Authorization in Support of Medical Policy

Avalon aspires to leverage our technology to minimize prior authorization requirements and increase physician satisfaction. In doing so, we are able to focus on:

- Automated enforcement of medical policy through claim edits supported by advances in coding specificity (i.e., ICD – 10), and access to clinical lab values providing reduced dependency upon Prior Authorization (PA)
- Complexity of some testing (i.e., Molecular) currently requires accumulation of clinical information
- Situations that endorse PA
  - Provider education
  - Medical policy
  - New technology
  - Fraud, waste and abuse identification/prevention
Application of Medical Policy: Prior Authorization

- BlueCross medical policies define tests at the CPT code level that:
  - Require prior authorization
  - Are covered without prior authorization
  - Are not covered

- Medical policies containing prior authorization elements:

<table>
<thead>
<tr>
<th>Test Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>BCR-ABL 1 Testing for Chronic Myeloid Leukemia</td>
<td>BRCA</td>
<td>Cardiac Ion Channelopathies</td>
<td>Chromosomal Microarray</td>
</tr>
<tr>
<td>Cytochrome P450</td>
<td>Epidermal Growth Factor Receptor</td>
<td>Familial Adenomatous Polyposis</td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td>FLT3 and NPM1 Mutation</td>
<td>General Genetic Testing</td>
<td>Genetic Testing for Cystic Fibrosis</td>
<td>HIV Genotyping and Phenotyping</td>
</tr>
<tr>
<td>JAK2 and MPL Mutation</td>
<td>KRAS and BRAF</td>
<td>Li-Fraumeni Syndrome</td>
<td>Lynch Syndrome</td>
</tr>
<tr>
<td>Non-invasive Prenatal Screening for Aneuploidy</td>
<td>Pre-implantation Genetic Testing</td>
<td>Prenatal Screening</td>
<td>PTEN Hamartoma Tumor Syndrome</td>
</tr>
</tbody>
</table>

- The full component of medical policies can be accessed at:

Avalon Prior Authorization (PA) Operations

Avalon’s utilization management staff are available Mon-Fri, 8:00am to 8:00pm EST

Avalon’s PA program is structured to operate consistently within the standards developed by CMS, URAC and NCQA

- Avalon will either approve, deny or request the specific clinical documentation necessary to complete the review
- Approvals and requests for additional information will be communicated to the requesting providers office
- Any adverse determinations will be verbally delivered in addition to the written letter sent to the member with copies to the ordering physician
- If additional information cited in an adverse determination notice is obtained pre-service, Avalon will review your request to see if the additional information meets criteria
- Member appeals will follow the existing BlueCross process

PA requests may be sent to Avalon effective January 1, 2016

- Phone: 1-844-227-5769
- Fax: 1-888-791-2181
  - Automated PA processing available 4/1/2016 via a connection to the Avalon provider portal
Case Study 1: Drive appropriate testing in AP

Surgical pathology profile

Clinical and reimbursement context
• 88305 often represents 10 – 15% of total health plan lab spend
• Unit of service is specimen rather than actual piece of tissue
• 31% of surg path billed in-office (or pod) labs (POS:11) with 43% coming from POS 22 and 25% coming from POS 81
• Commercials labs less predominant here than specialty AP labs

Prostate biopsies
• 48% of spend billed in-office (POS:11) and 35% from POS 81
• 89% of cost of all high-unit billing (10+ units) for 88305 is due to prostate biopsies

Self-referral differential
• Recent study indicates delta between number of specimens per biopsy across referral type

Prostate biopsy overview

Rules-based reimbursement
• Clinical evidence supports conditional cap of six units of specimens per prostate biopsy
• Precedent for this rule exists: Health plans deny reimbursement for 12-unit billing for prostate cores

Distribution by units billed

Utilization Management
• Intervention: prostate biopsy caps of 6 units
• Manage performance across all places of service

Billed specimens per prostate biopsy

Year 1

Year 2

Year 3

Self-referring urologist
Non-self referring urologists

Performance outlier

Annual Waste ($MM)

Low
$0.5

Med
$1.1

High
$1.6

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Case Study 2: Managing appropriate use of allergy testing

Domain review

• IgE allergy testing is medically necessary in many cases
• Tests are performed to check for allergies to specific allergens
• Tests are often ordered in large panels that include a variety of antibody-specific variants or units
• Panels consisting of 30-50+ units are clinically unjustifiable

Panels with more than 25 analytes account for 13% of claim volume and 29% of cost
Case Study 3: Facilitating appropriate testing in the molecular domain

- Testing algorithms in molecular testing start with evaluation of more common (high pre-test probability) mutations, before proceeding through exclusion or inclusion to evaluation of less common mutations
- Genetic tests today typically require physicians to order bundled genetic panels that test for both common and highly uncommon mutations together

<table>
<thead>
<tr>
<th>Condition</th>
<th>Current standard testing process</th>
<th>Reflexive approach</th>
<th>Efficiency Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMT neuropathy</td>
<td>Evaluates PMP22, MPZ, CMTX genes</td>
<td>Test for PMP22 mutation (70% of cases)</td>
<td>77%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Then test for other mutations</td>
<td></td>
</tr>
<tr>
<td>Friedrich’s ataxia</td>
<td>Evaluates both homozygous triplet repeats and point mutations</td>
<td>Test for triplet repeats (96% of cases)</td>
<td>43%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Then test for point mutations</td>
<td></td>
</tr>
<tr>
<td>Spino-cerebellar ataxia</td>
<td>Evaluates gene mutations for all 20 sub-types of disease</td>
<td>First test for SCA1,2,3,6,7</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Then test for other exceedingly rare mutations</td>
<td></td>
</tr>
<tr>
<td>EGFR mutation</td>
<td>Screening of all areas of gene to evaluate mutation.</td>
<td>Testing with targeted assays for deletions in exon 19 or L858R mutations in exon 21 (90% of testing)</td>
<td>45%</td>
</tr>
<tr>
<td></td>
<td>Commonly used to evaluate therapeutic match</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myelo-proliferative</td>
<td>Testing for rarer causal gene responsible for subset of diseases alongside more common point mutation</td>
<td>Test for point mutation JAK2 V617F first with cheaper directed test</td>
<td>51%</td>
</tr>
<tr>
<td>diseases</td>
<td></td>
<td>Then test for exons 12/13, then MPL mutations</td>
<td></td>
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Provider Management

Avalon thoughtfully collaborates with health plans to build a customized program that combines performance management, Centers of Excellence, and contracting scale.

Performance Management

- Promote transparency among lab network providers to improve quality
- Avalon educates providers on medical policy to ensure understanding and compliance
- Information used to assure right test is performed by the right lab

Centers of Excellence

- Academic, evidence-based lab medicine
- Clinical consultation is available with pathologists and genetic counselors
- Bridge to local hospital laboratories

Operational Scale

- Accumulate covered lives to promote consistency in cost and quality
- Drive acceptance of evidence-based medicine and adherence to medical policy protocols

Avalon aligns lab providers to medical policy and ultimately the goals of the health plan and its members through its provider management program.
Avalon Network Recruitment

Physicians and members will enjoy expanded access to select specialty lab providers through the Avalon network of labs.

The Avalon network of labs is offered as a supplement to the current BlueCross network. A comprehensive directory of laboratories participating in the BlueCross network is available on the BlueCross website.
Avalon / BlueCross Implementation

Key Points:
• Avalon was engaged by BlueCross to provide comprehensive laboratory benefits management services
• The new group of providers were added to the network to increase access to specialized testing
• All new and currently contracted providers, including LabCorp, Quest, and other large labs, are listed in the BlueCross directory
• Any future changes to the laboratory network will be communicated to the provider community as they occur
Avalon Provider Education:
Distribution Channels

- Webinars (2)
  - Introduction to Avalon and the Medical Policy Program
  - Direct peer presentation with Q&A

- Network Provider Representative
  - Plan representative or collaboration with Avalon network resource

- Newsletter
  - Plan newsletter and Avalon portal

- BlueCross provider manual
  - Information about the Avalon program to be included in the BlueCross provider manual