Complexities and Challenges in Managed Care

William J. Cardarelli, PharmD

ABSTRACT

OBJECTIVES: To (a) summarize the implications of human immunodeficiency virus (HIV) and Hepatitis B virus (HBV) guidelines for managed care, and (b) relate the challenges of caring for HIV, HBV, and HIV-HBV co-infected patients to managed care.

SUMMARY: The primary complexity for managed care related to human immunodeficiency virus (HIV) and/or hepatitis B virus (HBV) infection is that treatment guidelines, recommendations, and consensus statements are rapidly changing as new information emerges and that significant uncertainties remain. By 2017, total health care spending will be more than $4 trillion dollars per year, more than double the current level. One response of managed care is increasing use of cost-management tools, such as treatment guidelines, formulary restrictions, lists of preferred drugs, and implementation of disease management programs. A key component of programs to manage medication use involves the pharmacy benefit design. Altrius Health/Harvard Vanguard Medical Associates use an algorithm to make formulary decisions that explicitly incorporate the clinical value and cost-effectiveness of proposed additions.

CONCLUSIONS: For chronic diseases, such as HIV, HBV, and co-infections with HIV and HBV, an approach that encourages the implementation of strategies to improve the treatment of patients diagnosed with these conditions is needed. This approach should include empowering front-line clinicians in addressing issues around access to, persistence with, and adherence to therapy. The challenge to managed care in antiviral medications for HIV and HBV is similar to that in other chronic medication categories. Managed care organizations must evolve the drug benefit design to provide access to chronic medications that are recommended by evidence-based treatment guidelines and to provide the data to support and empower clinical improvement.

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anagement of chronic viral infections in managed care settings involves many complexities and challenges. The primary complexity is the large number of published treatment guidelines, recommendations, and consensus statements available for management of chronic infections, such as human immunodeficiency virus (HIV) and/or hepatitis B virus (HBV) infection. In addition, these guidelines change rapidly as new information emerges.

Guidelines for HIV and HBV, Including Co-Infected Patients

In the most recent revision of the U.S. Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents (DHHS Guidelines dated January 29, 2008)¹ recommend “preferred” and “alternative” antiretroviral components for treatment-naïve HIV-infected patients changed (Table 1).¹

In addition, the DHHS Guidelines now state that planned long-term therapy interruptions (sometimes called drug holidays) cannot be recommended because they may result in viral rebound, immune decompensation, and clinical progression; however, short-term interruptions of days to weeks may be necessary for various reasons, including toxicities or illnesses precluding oral therapy. Treatment for active or latent tuberculosis in HIV-infected patients should follow the same principles as for persons without

<table>
<thead>
<tr>
<th>Change</th>
<th>Context</th>
<th>Antiretroviral Agent(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not offer</td>
<td>Ever</td>
<td>Dual NNRTIs</td>
</tr>
<tr>
<td>No longer recommended</td>
<td>Initial therapy in treatment-naive patients</td>
<td>3TC and d4T, 3TC, ABC, and AZT, Nelfinavir</td>
</tr>
<tr>
<td>Downgraded to alternative</td>
<td>Use as dual nucleoside</td>
<td>3TC and AZT</td>
</tr>
<tr>
<td>Upgraded to alternative</td>
<td>Use as in initial HAART</td>
<td>Ritonavir-boosted saquinavir</td>
</tr>
<tr>
<td>Upgraded to preferred</td>
<td>In HLA-B*5701-negative patients only</td>
<td>3TC and ABC</td>
</tr>
<tr>
<td>Insufficient data as initial therapy</td>
<td>New NNRTI</td>
<td>Etravirine (TMC125)</td>
</tr>
<tr>
<td>New CCR5 antagonist</td>
<td>Maraviroc</td>
<td></td>
</tr>
<tr>
<td>New integrase inhibitor</td>
<td>Raltegravir</td>
<td></td>
</tr>
<tr>
<td>New PI</td>
<td>Ritonavir-boosted darunavir (TMC114)</td>
<td></td>
</tr>
<tr>
<td>Quadruple NRTI</td>
<td>3TC, ABC, AZT, and TDF</td>
<td></td>
</tr>
</tbody>
</table>

CTRL ± lamivudine, ABC = abacavir; AZT = zidovudine; CCR5 = chemokine (C-C motif) receptor 5; d4T = stavudine; HAART = highly active antiretroviral treatment; NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; PI = protease inhibitor; TDF = tenofovir.

Author

WILLIAM J. CARDARELLI, PHARM.D, is director of pharmacy, Harvard Vanguard Medical Associates and Altrius Health, in Watertown, Massachusetts.

AUTHOR CORRESPONDENCE: William J. Cardarelli, PharmD, Director of Pharmacy, Harvard Vanguard Medical Associates, Altrius Health, 485 Arsenal St., Watertown, MA 02472. Tel.: 617.972.5321; Fax: 617.972.5326; E-mail: William_cardarelli@vmed.org
HIV infection. The section of the guidelines on treatment of co-infection with HIV and hepatitis B or C viruses was unchanged in this revision.1

HIV guidelines have also been developed by other organizations, such as the World Health Organization (WHO), the New York State Department of Health AIDS Institute, and the International AIDS Society–United States of America (IAS–USA). A partial list is available from the HIV Medicine Association (hivma@idsociety.org).2

There is also a plethora of HBV guidelines and consensus statements. The American Association for the Study of Liver Diseases (AASLD) has approved and published practice guidelines for HBV infection that have been endorsed by the Infectious Diseases Society of America (IDSA).3 Other recent guidelines include the summary of a U.S. National Institutes of Health (NIH) clinical research workshop of management of HBV,4 an updated treatment algorithm for the management of chronic HBV infection in the United States,5 a roadmap for oral therapy based on an international workshop,6 and treatment of HBV-HIV co-infection from Europe.7 There have also been other algorithms proposed in the literature for co-infected patients.8

**Medication Use and Managed Care Response**

Medication use is a major challenge to managed care organizations due to the very high demand for prescription medications.9 As the baby-boomer generation ages, the Centers for Medicare and Medicaid Services (CMS) predict that by 2017 total health care spending will be more than $4 trillion dollars per year, more than double the current level. The cost of health care in 2017 is estimated to be $13,101 per person compared with $7,026 per person in 2006. Health care is projected to account for nearly one fifth (19.5%) of the gross domestic product.

One response of managed care is increasing use of cost-management tools, such as integrating evidence from treatment

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**Algorithm for Formulary Decision Making**

*Adapted from Atrius Health/Harvard Vanguard Medical Associates 2008*

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Drug review – oral/written presentation by clinical pharmacist

Experience/opinion – oral comments by invited consultants and committee members

Does drug offer substantial improvement in therapy over existing formulary drugs for like indications, or is it a completely new therapy for a disease not previously covered by medications?

Yes

Add to formulary with guidelines for cost-effective and safe use if needed.

No

Does drug offer at least equal clinical benefit to existing formulary drugs for like indications?

Yes

Can any safety concerns be managed?

Yes

Does financial impact of drug support formulary addition?

Yes

Add to formulary with guidelines for cost-effective use if needed.

No

Do not add to formulary.

No

Do not add to formulary.

No

Do not add to formulary.

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*Consider contract price/length and average wholesale price. Consider effect of decision on contracts of competing drugs. Consider tiers of major insurance payers.*
guidelines into formulary decisions or algorithms. Formulary restrictions and lists of preferred drugs are a key cost containment component as are implementation of disease management programs. Evidence-based medicine (EBM) is emerging to provide an underpinning for clinical practice, replacing clinical practices based on expert opinion and past practice patterns.

Measuring the clinical performance of physicians and health care organizations is critical. The National Committee for Quality Assurance (NCQA, www.ncqa.org), a private not-for-profit organization since 1990, provides programs and services reflecting a straightforward formula for improvement (Measure, Analyze, Improve, Repeat). The Bridges to Excellence (BTE, www.bridgestoexcellence.org), another non-profit organization, designs and creates programs that encourage physicians and physician practices to deliver safer and more effective care by providing financial and other incentives. The Agency for Health care Research and Quality (AHRQ, www.ahrq.gov) and the Centers for Medicare and Medicaid Services (CMS, www.cms.hhs.gov), both part of the DHHS, each provide a wealth of information about performance metrics and many other topics related to quality improvement in health care settings.

A key component of medication management programs involves the pharmacy benefit. Pharmacy benefit programs can be quite complex and include a variable number of benefit tiers (3, 4, 5, or more), as well as variations in co-insurance and co-payments. At the same time there are physician reimbursement and incentive programs that encourage the use of specific agents. It is conceivable that the tiering of pharmaceuticals and co-payments structure can be used to encourage improved care by being based on clinical value and improved outcomes rather than on being heavily weighted on cost, as well as formulary status in the traditional model. Prior authorization and step therapy are also used to call attention to the choices being made for therapy. The same approach could be used in the design of physician incentives. The traditional model also always assigns generic drugs the lowest co-payments and ranks preferred brands in the second tier and non-preferred brands in the third tier. This may be the time to consider tiering based more on clinical value than a brand-versus generic-ranking system.

### Making Formulary Decisions

At Altrius Health/Harvard Vanguard Medical Associates, the P&T Committee uses an algorithm to make formulary decisions that explicitly incorporates the clinical value and cost-effectiveness of proposed additions (Figure). The first decision is whether the proposed medication offers substantial improvement over medications on the formulary for similar indications or is for a new indication not previously treated. If so, it is added to the formulary. If not, the proposed drug will be added to the formulary only (1) if it offers at least equal benefit to existing formulary drugs, (2) if safety concerns can be managed, and, finally, (3) if the financial impact supports formulary addition. This financial impact includes several factors, such as rebates, current formulary status, and restrictions (i.e., prior authorizations). The contract price and length of the contract, as well as impact on contracts with competing drugs and the tiers of major insurance payers, are also considered.

Antiviral drugs account for an increasing share of medication costs. The trend in ARV spending is projected to increase by 12.3% in 2008, the same rate as in 2006 and 2007. This reflects an increase in unit costs because utilization growth was slow (4.7%). Other data indicate that the use of combination products contributed to the strong spending growth. Several managed care companies and pharmacies have implemented programs in specialty pharmacy management in order to control this trend in utilization growth. It is also important to monitor costs of these conditions as disease progression can be costly, as well as difficult for the patient. Not keeping an eye on proper management of these conditions can prematurely worsen the conditions due to under-treatment.

### Summary

For chronic diseases, such as HIV, HBV, and HIV/HBV co-infection, a chronic care treatment approach that promotes patient adherence issues is required. In patients with HIV, reduced adherence to HIV medications was driven by dosing (14% by the daily pill burden and 13% by dosing frequency), adverse events (12%), dietary restrictions (11%), and pill size (10%). The number of co-payments and other prescription-related issues was less important to medication adherence, though they still contributed to less than optimal adherence.

The challenge to managed care in antiviral medications for HIV and HBV is similar to that in other chronic medication categories. Managed care organizations must evolve the drug benefit design to provide access to medications that are recommended by evidence-based treatment guidelines. These guidelines must be published and distributed. Furnishing physicians and other stakeholders with utilization data and rewarding best practices is essential.

### REFERENCES


