



## Therapeutic Class Review<sup>SM</sup>

### Antiviral Therapy in HIV Infection: Atripla<sup>TM</sup>

December 2006

**New Product for Review:**

efavirenz/emtricitabine/tenofovir  
(Atripla<sup>TM</sup>) [Bristol-Myers Squibb and Gilead]

**Dossier Provided by Manufacturer: Yes**

**Dossier Evaluation: 3**

- 1- dossier w/missing components
- 2- all components present, except pharmaco-economic model
- 3- all components present (comprehensive)

**Available Therapeutic Alternatives:**

| Preferred/Formulary   | Non-Preferred/Non-Formulary                              |
|---|--|
| <b>Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs):</b> |  |
| delavirdine (Rescriptor <sup>®</sup> ) [Pfizer]                 |  |
| efavirenz (Sustiva <sup>®</sup> ) [Bristol-Myers Squibb (BMS)]  |  |
| nevirapine (Viramune <sup>®</sup> ) [Boehringer Ingelheim]      |  |
| <b>Nucleoside Reverse Transcriptase Inhibitors (NRTIs):</b>     |  |
| abacavir (Ziagen <sup>®</sup> ) [GlaxoSmithKline (GSK)]         | emtricitabine/tenofovir (Truvada <sup>®</sup> ) [Gilead] |
| abacavir/lamivudine (Epzicom <sup>®</sup> ) [GSK]               |  |
| abacavir/lamivudine/zidovudine (Trizivir <sup>®</sup> ) [GSK]   |  |
| didanosine (Videx <sup>®</sup> ) [BMS]                          |  |
| didanosine enteric coated (Videx <sup>®</sup> EC) [generic]     |  |
| emtricitabine (Emtriva <sup>®</sup> ) [Gilead]                  |  |
| lamivudine (Epivir <sup>®</sup> ) [GSK]                         |  |
| lamivudine/zidovudine (Combivir <sup>®</sup> ) [GSK]            |  |
| stavudine (Zerit <sup>®</sup> ) [BMS]                           |  |
| tenofovir (Viread <sup>®</sup> ) [Gilead]                       |  |
| zalcitabine (Hivid <sup>®</sup> ) [Roche]                       |  |
| zidovudine (Retrovir <sup>®</sup> ) [generic]                   |  |

## Available Therapeutic Alternatives (Continued):

| <b>Protease Inhibitors (PIs):</b>                    |   |
|--|---|
| amprenavir (Agenerase <sup>®</sup> ) [GSK/Vertex]    | darunavir (Prezista <sup>™</sup> ) [Tibotec]  |
| atazanavir (Reyataz <sup>®</sup> ) [BMS]             | tipranavir (Aptivus <sup>®</sup> ) [Boehringer Ingelheim]   |
| fosamprenavir (Lexiva <sup>®</sup> ) [GSK/Vertex]    |   |
| indinavir (Crixivan <sup>®</sup> ) [Merck]           |   |
| lopinavir/ritonavir (Kaletra <sup>®</sup> ) [Abbott] |   |
| nelfinavir (Viracept <sup>®</sup> ) [Pfizer]         |   |
| ritonavir (Norvir <sup>®</sup> ) [Abbott]            |   |
| saquinavir (Invirase <sup>®</sup> ) [Roche]          |   |
| <b>Fusion Inhibitors:</b>                            |   |
| enfuvirtide (Fuzeon <sup>®</sup> ) [Roche/Trimeris]  |   |
| <b>Combination NNRTIs plus NRTIs:</b>                |   |
|  | efavirenz/emtricitabine/tenofovir (Atripla <sup>™</sup> )<br>[Bristol-Myers Squibb & Gilead Sciences] |

### Executive Summary

- Atripla is a combination of three antiretroviral agents: efavirenz (Sustiva), a non-nucleoside reverse transcriptase inhibitor (NNRTI), and two nucleoside reverse transcriptase inhibitors (NRTIs), emtricitabine (Emtriva) and tenofovir (Viread).
- The components in Atripla are considered first-line in the treatment of HIV-1 infection in treatment-naïve patients.
- The manufacturer promotes this product as a convenient, single tablet, once-daily regimen.
- The U.S. FDA encourages the development of HIV therapies that improve adherence to therapy because high rates of adherence are associated with virologic success.
- Improved adherence in HIV therapy is related to decreased pill burden, decreased frequency of administration, and improved tolerability of the regimen. These practical considerations are included in determining the overall value of the medication (see Appendix J).
- A single dose of Atripla is bioequivalent with its individual components given together at the same time.
- The cost of Atripla is similar to the individual components that make up this combination product.

### Evidence

- There is no useful evidence (open-label study design) supporting the efficacy of the combination of antiretroviral agents found in Atripla in treatment-naïve HIV-infected adults.
- There is no useful evidence (open-label study design) available to assess the safety and tolerability of Atripla relative to alternative antiretroviral regimens.
- There are no studies demonstrating improved adherence with Atripla over the individual components taken separately, or over other NRTI-based regimens.

**Consideration in subpopulations:**

- *Pediatrics:* The safety and efficacy of Atripla have not been established in patients less than 18 years of age.
- *Geriatrics:* There is insufficient evidence to determine whether patients aged 65 years and over respond differently than younger populations.
- *Race, ethnicity, or gender:* Current clinical experience has not identified differences in safety or efficacy based on race, ethnicity or gender.

**Conclusion**

Atripla is preferred/formulary because:

- The individual components of Atripla are established as first-line agents in treatment-naïve HIV patients.
- There is no additional cost for Atripla over the cost of its individual components.

**Products**

**Table 1:**

| Drug Product  | Date of FDA Approval | FDA Approved Indication   | Dose/Route  | AWP Cost*          | Potential Off-Label Uses                    |
|---|----------------------|---|---|--------------------|---|
| <b>Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs):</b>                       |                      |   |   |                    |   |
| delavirdine (Rescriptor®) <sup>1, 29</sup>  | 4/1997               | Treatment of HIV-1 infection in combination with at least two other active antiretroviral agents.                 | 400 mg p.o. t.i.d   | \$317              | occupational HIV post-exposure prophylaxis  |
| efavirenz (Sustiva®) <sup>2, 29</sup>   | 9/1998               | Treatment of HIV-1 infection in combination with other antiretroviral medications (combine with a PI +/-or NRTI). | 600 mg p.o. q.d. [empty stomach]                                    | \$520              | occupational HIV post-exposure prophylaxis  |
| nevirapine (Viramune®) <sup>3, 29</sup>   | 6/1996               | Treatment of HIV-1 infection in combination with other antiretroviral medications.                                | 200 mg p.o. q.d. x 14 days, then b.i.d.                             | \$463              | perinatal and postnatal transmission of HIV |
| <b>Nucleoside Reverse Transcriptase Inhibitors (NRTIs):</b>                           |                      |   |   |                    |   |
| abacavir (Ziagen®) <sup>4, 29</sup>   | 12/1998              | Treatment of HIV-1 infection in combination with other antiretroviral medications.                                | 300 mg p.o. b.i.d. or 600 mg p.o. q.d.                              | \$492              | occupational HIV post-exposure prophylaxis  |
| abacavir/lamivudine (Epzicom®) <sup>5, 29</sup><br>[600 mg/300 mg]                    | 8/2004               | Treatment of HIV-1 infection in combination with other antiretroviral medications.                                | 1 tablet p.o. q.d.  | \$857              | occupational HIV post-exposure prophylaxis  |
| abacavir/lamivudine/zidovudine (Trizivir®) <sup>6, 29</sup><br>[300 mg/150 mg/300 mg] | 11/2000              | Treatment of HIV-1 infection alone or in combination with other antiretroviral medications.                       | 1 tablet p.o. b.i.d.  | \$1286             | occupational HIV post-exposure prophylaxis  |
| didanosine (Videx®) <sup>7, 29</sup>  | 10/1991              | Treatment of HIV-1 infection in combination with other antiretroviral medications.                                | ≥ 60 kg: 200 mg b.i.d.<br>< 60 kg: 125 mg b.i.d.<br>[empty stomach] | \$307<br>\$192     | occupational HIV post-exposure prophylaxis  |
| didanosine [generic] (Videx EC®) <sup>8, 29</sup>                                     | 10/2000              | Treatment of HIV-1 infection in combination with other antiretroviral medications.                                | ≥ 60 kg: 400 mg q.d.<br>< 60 kg: 250 mg q.d.<br>[empty stomach]     | \$237 †<br>\$154 † | occupational HIV post-exposure prophylaxis  |

\* AWP (average wholesale price) based on First Data Bank as of September 2006 for 30 days of therapy.

† MAC = maximum allowable cost as of September 2006 for 30 days of therapy.

**Table 1 (continued):**

| Drug Product  | Date of FDA Approval | FDA Approved Indication  | Dose/Route   | AWP Cost*                              | Potential Off-Label Uses   |
|---|----------------------|--|--|--|--|
| <b>Nucleoside Reverse Transcriptase Inhibitors (NRTIs) (Continued):</b> |                      |  |  |  |  |
| emtricitabine (Emtriva®) <sup>9, 29</sup>                               | 7/2003               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 200 mg p.o. q.d.   | \$366                                  | Hepatitis B infection  |
| emtricitabine/tenofovir (Truvada®) <sup>10, 29</sup><br>[200 mg/300 mg] | 8/2004               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 1 tablet p.o. q.d.   | \$919                                  | Hepatitis B infection  |
| lamivudine (EpiVir®) <sup>11, 29</sup>                                  | 11/1995              | 1) Treatment of HIV-1 infection in combination with other antiretroviral medications.<br>2) Hepatitis B (EpiVir HBV)                         | 150 mg p.o. b.i.d. or<br>300 mg p.o. q.d.                                    | \$366                                  | occupational HIV post-exposure prophylaxis; Perinatal and postnatal trans-mission of HIV       |
| lamivudine/zidovudine (Combivir®) <sup>12, 29</sup><br>[150 mg/300 mg]  | 9/1997               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 1 tablet p.o. b.i.d.   | \$794                                  | perinatal HIV transmission prevention  |
| stavudine (Zerit®) <sup>13, 29</sup>                                    | 6/1994               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | ≥ 60 kg: 40 mg b.i.d.<br>< 60 kg: 30 mg b.i.d.<br>(every 12 hours)           | \$402<br>\$394                         | occupational HIV post-exposure prophylaxis   |
| tenofovir (Viread®) <sup>14, 29</sup>                                   | 10/2001              | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 300 mg p.o. q.d.   | \$554                                  | Hepatitis B  |
| zalcitabine (Hivid®) <sup>15, 29</sup>                                  | 6/1992               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 0.75 mg p.o. q. 8 hrs  | \$260                                  |  |
| zidovudine [generic] (Retrovir®) <sup>16, 29</sup>                      | 3/1987               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 300 mg p.o. b.i.d. or<br>200 mg p.o. t.i.d.                                  | \$163 †<br>\$304 †                     | occupational HIV post-exposure prophylaxis; Hepatitis B; perinatal HIV transmission prevention |
| <b>Protease Inhibitors (PIs):</b>                                       |                      |  |  |  |  |
| amprenavir (Agenerase®) <sup>17, 29</sup>                               | 4/1999               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 1200 mg p.o. b.i.d.<br>(decrease by 50% if given with ritonavir)             | \$772                                  | occupational HIV post-exposure prophylaxis   |
| atazanavir (Reyataz®) <sup>18, 29</sup>                                 | 6/2003               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 400 mg p.o. q.d.<br>300 mg p.o. q.d.<br>(with ritonavir)<br>[take with food] | \$929<br>\$929                         |  |
| darunavir (Prezista™) <sup>19, 29</sup>                                 | 6/2006               | Treatment of HIV-1 infection in combination with ritonavir and other antiretroviral agents in antiretroviral treatment-experienced patients. | 600 mg p.o. b.i.d. plus<br>ritonavir 100 mg b.i.d.<br><br>[take with food]   | \$1580<br>(includes cost of ritonavir) |  |
| fosamprenavir (Lexiva®) <sup>20, 28</sup>                               | 10/2003              | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 1400 mg p.o. b.i.d.<br>(decrease by 50% if given with ritonavir)             | \$1390                                 |  |
| indinavir (Crixivan®) <sup>21, 29</sup>                                 | 3/1996               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 800 mg p.o. q. 8 hrs<br>[empty stomach]                                      | \$571                                  | occupational HIV post-exposure prophylaxis   |

\* AWP (average wholesale price) based on First Data Bank as of September 2006 for 30 days of therapy.

† MAC = maximum allowable cost as of September 2006 for 30 days of therapy.

**Table 1 (continued):**

| Drug Product  | Date of FDA Approval | FDA Approved Indication  | Dose/Route   | AWP Cost*                              | Potential Off-Label Uses                   |
|---|----------------------|--|--|--|--|
| <b>Protease Inhibitors (PIs) (Continued):</b>   |                      |  |  |  |  |
| lopinavir/ritonavir (Kaletra <sup>®</sup> ) <sup>22, 29</sup><br>[133.3 mg/33.3 mg]                     | 9/2000               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 3 caps p.o. b.i.d. or 6 caps p.o. q.d.<br>[with food]                          | \$797<br>\$797                         | occupational HIV post-exposure prophylaxis |
| nelfinavir (Viracept <sup>®</sup> ) <sup>23, 29</sup>   | 3/1997               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 1250 mg p.o. b.i.d. or 750 mg t.i.d.<br>[with food]                            | \$757<br>\$840                         | occupational HIV post-exposure prophylaxis |
| ritonavir (Norvir <sup>®</sup> ) <sup>24, 29</sup>  | 3/1996               | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 600 mg p.o. b.i.d.<br>[\$10.72 per 100 mg cap]                                 | \$3858<br>[\$643]                      | occupational HIV post-exposure prophylaxis |
| saquinavir (Invirase <sup>®</sup> ) <sup>26, 29</sup>   | 12/1995              | Treatment of HIV-1 infection in combination with other antiretroviral medications.   | 1000 mg p.o. b.i.d. + ritonavir 100 mg b.i.d.<br>[with food]                   | \$1466                                 | occupational HIV post-exposure prophylaxis |
| tipranavir (Aptivus <sup>®</sup> ) <sup>27, 29</sup>  | 6/2005               | Treatment of HIV-1 infection in combination with ritonavir in patients with evidence of viral replication that are highly treatment-experienced or have HIV-1 strains resistant to multiple protease inhibitors. | 500 mg p.o. b.i.d. co-administered with ritonavir 200 mg b.i.d.<br>[with food] | \$2404<br>(includes cost of ritonavir) |  |
| <b>Fusion Inhibitors:</b>   |                      |  |  |  |  |
| enfuvirtide (Fuzeon <sup>®</sup> ) <sup>27, 29</sup>  | 3/2003               | Treatment of HIV-1 infection in combination with other antiretroviral medications in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.                   | 90 mg (1 ml) subcutaneously b.i.d.   | \$2432                                 |  |
| <b>Combination NNRTIs plus NRTIs:</b>   |                      |  |  |  |  |
| efavirenz/emtricitabine/tenofovir (Atripla <sup>™</sup> ) <sup>28, 29</sup><br>[600 mg/ 200 mg/ 300 mg] | 7/2006               | Treatment of HIV-1 infection alone as a complete regimen, or in combination with other antiretroviral agents in adult patients.  | 1 tablet p.o. daily [empty stomach]  | \$1439                                 |  |

\*AWP (average wholesale price) based on First Data Bank as of September 2006 for 30 days of therapy.

† MAC = maximum allowable cost as of September 2006 for 30 days of therapy.

**Table 2:**

| <b>Drug Product</b>   | <b>Approval in pediatric patients</b> | <b>Minimum age of approval<sup>#</sup></b> | <b>Pregnancy category</b> |
|---|---------------------------------------|--|---------------------------|
| <b>NNRTIs:</b>  |                                       |  |                           |
| delavirdine (Rescriptor <sup>®</sup> ) <sup>1</sup>                     |                                       |  | Category C                |
| efavirenz (Sustiva <sup>®</sup> ) <sup>2</sup>                          | <b>X</b>                              | ≥ 3 years                                  | Category D                |
| nevirapine (Viramune <sup>®</sup> ) <sup>3</sup>                        | <b>X</b>                              | ≥ 2 months                                 | Category C                |
| <b>NRTIs:</b>   |                                       |  |                           |
| abacavir (Ziagen <sup>®</sup> ) <sup>4</sup>                            | <b>X</b>                              | ≥ 3 months                                 | Category C                |
| abacavir/lamivudine (Epzicom <sup>®</sup> ) <sup>5</sup>                |                                       |  | Category C                |
| abacavir/lamivudine/zidovudine (Trizivir <sup>®</sup> ) <sup>6</sup>    |                                       |  | Category C                |
| didanosine (Videx <sup>®</sup> ) <sup>7</sup>                           | <b>X</b>                              | ≥ 2 weeks                                  | Category B                |
| didanosine enteric coated (Videx <sup>®</sup> EC) <sup>8</sup>          |                                       |  | Category B                |
| emtricitabine (Emtriva <sup>®</sup> ) <sup>9</sup>                      |                                       |  | Category B                |
| emtricitabine/tenofovir (Truvada <sup>®</sup> ) <sup>10</sup>           |                                       |  | Category B                |
| lamivudine (EpiVir <sup>®</sup> ) <sup>11</sup>                         | <b>X</b>                              | ≥ 3 months                                 | Category C                |
| lamivudine/zidovudine (Combivir <sup>®</sup> ) <sup>12</sup>            |                                       |  | Category C                |
| stavudine (Zerit <sup>®</sup> ) <sup>13</sup>                           | <b>X</b>                              | from birth                                 | Category C                |
| tenofovir (Viread <sup>®</sup> ) <sup>14</sup>                          |                                       |  | Category B                |
| zalcitabine (Hivid <sup>®</sup> ) <sup>15</sup>                         | <b>X</b>                              | ≥ 13 years                                 | Category C                |
| zidovudine (Retrovir <sup>®</sup> ) <sup>16</sup>                       | <b>X</b>                              | from birth (intravenous)                   | Category C                |
| <b>Protease Inhibitors (PIs):</b>                                       |                                       |  |                           |
| amprenavir (Agenerase <sup>®</sup> ) <sup>17</sup>                      | <b>X</b>                              | ≥ 4 years                                  | Category C                |
| atazanavir (Reyataz <sup>®</sup> ) <sup>18</sup>                        |                                       |  | Category B                |
| darunavir (Prezista <sup>™</sup> ) <sup>19</sup>                        |                                       |  | Category B                |
| fosamprenavir (Lexiva <sup>®</sup> ) <sup>20</sup>                      |                                       |  | Category C                |
| indinavir (Crixivan <sup>®</sup> ) <sup>21</sup>                        |                                       |  | Category C                |
| lopinavir/ritonavir (Kaletra <sup>®</sup> ) <sup>22</sup>               | <b>X</b>                              | ≥ 6 months                                 | Category C                |
| nelfinavir (Viracept <sup>®</sup> ) <sup>23</sup>                       | <b>X</b>                              | ≥ 2 years                                  | Category B                |
| ritonavir (Norvir <sup>®</sup> ) <sup>24</sup>                          | <b>X</b>                              | ≥ 2 years                                  | Category B                |
| saquinavir (Invirase <sup>®</sup> ) <sup>25</sup>                       |                                       |  | Category B                |
| tipranavir (Aptivus <sup>®</sup> ) <sup>26</sup>                        |                                       |  | Category C                |
| <b>Fusion Inhibitors:</b>   |                                       |  |                           |
| enfuvirtide (Fuzeon <sup>®</sup> ) <sup>27</sup>                        | <b>X</b>                              | ≥ 6 years                                  | Category B                |
| <b>Combination NNRTIs plus NRTIs:</b>                                   |                                       |  |                           |
| efavirenz/emtricitabine/tenofovir (Atripla <sup>™</sup> ) <sup>28</sup> |                                       |  | Category D                |

<sup>#</sup> see prescribing information for pediatric dosing of individual products.

## References

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