



Therapeutic Class ReviewSM

Antineoplastics: erlotinib (TarcevaTM)

July 2005

New Product for Review:

erlotinib (TarcevaTM) [Genentech]

Dossier Provided by Manufacturer: Yes

Quality of Dossier: 3 – High Quality

- 1 - Low quality (dossier w/missing component)
- 2 - Medium quality (all components, except pharmacoeconomic model)
- 3 - High quality (all components, well done)

Executive Summary:

- Platinum-based chemotherapy combinations have demonstrated the best overall survival rates (ranging from 8 to 14 months) among the agents currently used to treat advanced NSCLC and are considered first-line treatment options.
- Erlotinib (Tarceva) demonstrated a statistically significant survival benefit over placebo (6.7 versus 4.7 months) when it was administered to patients who experienced disease progression during or after first-line therapy for NSCLC.
- There was no additional clinical benefit seen when erlotinib (Tarceva) was added to cisplatin-based combination regimens in the first-line treatment of advanced NSCLC.
- Erlotinib (Tarceva) is approved as a 2nd- or 3rd-line agent for the treatment of advanced NSCLC.
- There is no evidence that demonstrates either inferior or superior efficacy of Tarceva over other second-line therapies for NSCLC.
- Gefitinib (Iressa), an antitumor drug for treatment of NSCLC with properties similar to those of erlotinib (Tarceva), has not demonstrated any survival benefit in clinical trials.
- The most prevalent adverse effects observed in patients taking erlotinib (Tarceva) were rash and diarrhea.

Decision:

The Committee unanimously voted to add Tarceva as preferred/formulary.

I. Products

Drug Product	Date of FDA Approval	FDA Approved Indication	Dose/Route	Potential Off-Label Uses
erlotinib (Tarceva™) ^{1,3}	11/2004	Treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.	150 mg orally once daily	colon cancer, cancer of the head and neck, breast cancer, ovarian carcinoma, pancreatic carcinoma, renal-cell carcinoma
gefitinib (Iressa®) ^{2,3} Note: Iressa will only be available through the <i>Iressa Access Program</i> after September 15, 2005.	5/2003	Monotherapy for the continued treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies who are benefiting or have benefited from Iressa.	250 mg orally once daily	mesothelioma, other solid tumors known to express epidermal growth factor receptor (EGFR)

References

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5. Product Dossier: Tarceva™ (erlotinib HCl). Genentech, Inc; South San Francisco, CA. Data reviewed 4/07/2005.
6. NCCN® Clinical Practice Guidelines in Oncology, Non-small cell lung cancer v.2.2005. National Comprehensive Cancer Network 2005. Available at: http://www.nccn.org/professionals/physician_gls/PDF/nscl.pdf. Accessed on 4/14/2005.
7. Herbst RS, Prager D, Hermann R, et al. TRIBUTE-A Phase III trial of erlotinib HCl (OSI-774) combined with carboplatin and paclitaxel (CP) chemotherapy in advanced non-small cell lung cancer (NSCLC). Proc Am Soc Clin Oncol 2004;23:ASCO Abstract #7011.
8. Gatzemeier U, Pluzanska A, Szczesna A, et al. Results of a Phase III trial of erlotinib (OSI-774) combined with cisplatin and gemcitabine (GC) chemotherapy in advanced non-small cell lung cancer (NSCLC). Proc Am Soc Clin Oncol 2004;23:ASCO Abstract #7010.
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10. Taxotere® (docetaxel) Product Information. Bridgewater, NJ: Aventis Pharmaceuticals Inc, 2004.
11. Alimta® (pemetrexed) Product Information. Indianapolis, IN: Eli Lilly and Company, 2004.
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