



## New Drug Indications/ Warnings (List- 5/2/2016 to 9/13/ 2016) Review for October 17, 2016

(New Drug Indications/ Boxed Warnings: FDA)

| Generic Name  | Trade Name        | Indication(s)   | CPG Action/Date                               |
|---|-------------------|---|---|
| Budesonide<br><br>(expanded indication)             | Entocort EC       | <i>Endocrine and Metabolic Agents:<br/>Adrenocortical Steroids;<br/>Glucocorticoids</i>                         | <b>Current: CTP holder may prescribe</b>      |
| Albuterol (salbutamol)<br><br>(expanded indication) | ProAir RespiClick | <i>Respiratory Agents:<br/>Bronchodilators;<br/>Sympathomimetics</i>  | <b>Current: CTP holder may prescribe</b>      |
| Ibrutinib<br><br>(expanded indication)              | Imbruvica         | <i>Therapeutic Categories:<br/>Antineoplastic Agents;<br/>Kinase Inhibitors;<br/>Tyrosine Kinase Inhibitors</i> | <b>Current: CTP holder may not prescribe</b>  |
| Olanzapine (safety alert)                           | ZyPrexa           | Central Nervous System Agents:<br>Antipsychotic Agents;<br>Second Generation (Atypical).                        | <b>Current: CTP holder may prescribe</b>      |
| Fluoroquinolones:<br><br>(safety alert)             |                   | <i>Anti-infective Agents:</i>   | <b>Current: CTP holder may prescribe</b>      |
| Lenvatinib<br><br>(expanded indication)             | Lenvima           | <i>Antineoplastic Agents:<br/>Kinase Inhibitors;<br/>Tyrosine Kinase Inhibitors</i>                             | <b>Current: CTP holder may not prescribe</b>  |
| Nivolumab<br><br>(expanded indication)              | Opdivo            | <i>Antineoplastic Agents:<br/>Monoclonal Antibodies (antineoplastic)</i>  | <b>Current: CTP holder may not prescribe.</b> |
| Canagliflozina<br><br>(safety alert)                | Invokana          | <i>Endocrine and Metabolic Agents:<br/>Antidiabetic Agents;<br/>Sodium-Glucose Co-Transporter 2 Inhibitors</i>  | <b>Current: CTP holder may prescribe</b>      |
| Dapagliflozin                                       | Farxiga           | <i>Endocrine and</i>  | <b>Current: CTP</b>                           |

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| (safety alert)  |            | <i>Metabolic Agents:<br/>Antidiabetic Agents;<br/>Sodium-Glucose Co-<br/>Transporter 2<br/>Inhibitors</i>     | <b>holder may<br/>prescribe</b>   |
| Rosuvastatin<br><br>(expanded<br>indication)                                    | Crestor    | <i>Cardiovascular<br/>Agents:<br/>Antihyperlipidemic<br/>Agents; HMG-COA<br/>Reductase Inhibitors</i>         | <b>Current: CTP<br/>holder may<br/>prescribe</b>  |
| Ceftaroline Fosamil<br><br>(expanded<br>indication)                             | Teflaro    | <i>Anti-Infective Agents;<br/>Cephalosporins</i>  | <b>Current: CTP<br/>holder may<br/>prescribe</b>  |
| Dolutegravir<br><br>(expanded<br>indication)                                    | Tivicay    | <i>Anti-infectives:<br/>Antiretroviral Agents;<br/>Integrase Inhibitors</i>                                   | <b>Current: (need<br/>discussion<br/>regarding listing<br/>subcategory<br/>"integrase<br/>inhibitors.")</b> |
| Adalimumab<br><br>(expanded<br>indication)                                      | Humira     | <i>Biologic and<br/>Immunological Agents:<br/>Immunologic Agents;<br/>Immunomodulators</i>                    | <b>Current: In<br/>accordance with<br/>the SCA</b>  |
| Omalizumab<br><br>(expanded<br>indication)                                      | Xolair     | <i>Respiratory Agents:<br/>Monoclonal Antibodies<br/>(Respiratory)</i>  | <b>Current: In<br/>accordance with<br/>the SCA</b>  |
| Pneumococcal<br>conjugate vaccine,<br>13 valent<br><br>(expanded<br>indication) | Prevnar 13 | <i>Biologic and<br/>Immunological Agents:<br/>Agents for Active<br/>Immunization:<br/>Vaccines, Bacterial</i> | <b>Current: CTP<br/>holder may<br/>prescribe</b>  |
| Dexlansoprazole<br><br>(expanded<br>indication)                                 | Dexilant   | <i>Gastrointestinal<br/>Agents: Proton Pump<br/>Inhibitors</i>  | <b>Current: CTP<br/>holder may<br/>prescribe</b>  |
| C1 Inhibitor, Human<br><br>(expanded<br>indication)                             | Berinert   | <i>Hematologic Agents:<br/>Protein C1 Inhibitors</i>  | <b>Current: In<br/>accordance with<br/>the SCA</b>  |
| Riboflavin 5-<br>Phosphate<br><br>(expanded                                     | Photrex    | <i>Ophthalmic and Otic<br/>Agents: Ophthalmic<br/>Surgical Adjuncts</i>                                       | <b>Current: CTP<br/>holder may not<br/>prescribe</b>  |

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| indication)                                 |             |  |   |
| AbobotulinumtoxinA<br>(expanded indication) | Dysport     | Central Nervous System Agents;<br>Botulinum Toxins:<br>Botulinum Toxin Type A                      | <b>Current: In accordance with the SCA</b>    |
| Pembrolizumab<br>(expanded indication)      | Keytruda    | <i>Biologic and Immunological Agents:<br/>Immunologic Agents;<br/>Immunomodulators</i>             | <b>Current: CTP holder may not prescribe</b>  |
| Topiramate<br>(expanded indication)         | Trokendi XR | <i>Central Nervous System Agents:<br/>Anticonvulsants</i>  | <b>Current: CTP holder may prescribe</b>      |
| Blinatumomab                                | Blinicyto   | Antineoplastic Agents;<br>Monoclonal Antibodies(antineoplastic)                                    | <b>Current: CTP holder may not prescribe.</b> |
| ofatumumab                                  | Arzerra     | Antineoplastic Agents;<br>Monoclonal Antibodies(antineoplastic).                                   | <b>Current: CTP holder may not prescribe.</b> |
| pegloticase                                 | Krystexxa   | <i>Endocrine and Metabolic Agents;<br/>Agents for Gout.</i>  | <b>CTP holder may prescribe.</b>              |
| Influenza A (H5N1) Immunization             |             | <i>Biologic and Immunological Agents:<br/>Agents for Active Immunization;<br/>Vaccines, Viral:</i> | <b>CTP holder may prescribe</b>               |