**March 2015**

*The following changes to the Neighborhood formulary were recently approved by the Pharmacy and Therapeutics (P&T) Committee. These changes are effective immediately unless otherwise indicated.*

<table>
<thead>
<tr>
<th>Therapeutic Class/Drug Name</th>
<th>Strategy or Medications Added or Modified</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpromazine</td>
<td>Do not remove chlorpromazine from Formulary; require Prior Authorization. Prior Authorization criteria for chlorpromazine require failure of at least two alternative Formulary antipsychotic agents.</td>
<td>Chlorpromazine is a first-generation antipsychotic agent that does not carry a unique indication compared to alternatives available on Formulary. Chlorpromazine is associated with increased severity of side effects compared to other first generation antipsychotics, such as sedation, anticholinergic effects and orthostatic hypotension. Chlorpromazine is associated with increased extrapyramidal side effects compared to second generation antipsychotics. First and second generation antipsychotics covered without any restrictions include haloperidol, perphenazine, risperidone, olanzapine, quetiapine and ziprasidone. Chlorpromazine is significantly more expensive than alternative Formulary agents.</td>
</tr>
<tr>
<td>Celecoxib (Celebrex®)</td>
<td>Add celecoxib to Formulary; require Step-Therapy with at least three Formulary non-steroidal anti-inflammatory drugs (NSAIDs), unless contraindicated. Implement a quantity limit of #30 capsules per prescription.</td>
<td>Celecoxib is an alternative NSAID available for those patients whom require therapy with an anti-inflammatory, but who are either not able to obtain an adequate outcome with, or contraindicated to, alternative Formulary NSAIDs. Meloxicam, naproxen, diclofenac sodium and ibuprofen are oral NSAIDs covered without any restrictions. Since becoming available generically in December 2014, the average price per prescription for celecoxib has decreased significantly compared to the brand product Celebrex and other generic non-Formulary NSAIDs. Quantities of celecoxib in excess of #30 may be requested through the Prior Authorization process.</td>
</tr>
<tr>
<td>Elidel &amp; Tacrolimus (Protopic) ointment</td>
<td>Update Medical Necessity Criteria (MNC) to require failure of at least two topical steroids (Class V to I) and tacrolimus ointment. Implement a quantity limit of 30g/Rx for Elidel and tacrolimus ointment.</td>
<td>Tacrolimus (Protopic) is now available generically. Both tacrolimus ointment and Elidel are topical immunosuppressants indicated for the treatment of atrophic dermatitis. The requirement of failure of tacrolimus prior to Elidel is in line with the State of RI generics-first mandate. Tacrolimus is covered through the Prior Authorization process following recent failure of at least two topical steroids (class V to I).</td>
</tr>
</tbody>
</table>
## Angiotensin Receptor Blocker (ARB) & combination agents (all)
- Benicar
- Edarbi
- Candesartan
- Telmisartan

**Update ARB Medical Necessity Criteria (MNC) to require failure of at least two Formulary ARBs and at least one angiotensin converting enzyme (ACE) inhibitor.**

Losartan and irbesartan are Formulary ARBs, covered without any restrictions. Non-Formulary ARBs have not been shown to provide additional clinical benefit over Formulary ARBs and ACE-inhibitors. Non-Formulary ARBs are significantly more expensive than Formulary alternatives.

## DPP-4 Inhibitors & combination agents (all)
- Januvia
- Janumet
- Jentadueto
- Kombiglyze XR
- Nesina
- Onglyza
- Oseni
- Tradjenta

**Update DPP-4 inhibitor Medical Necessity Criteria (MNC) to require failure of insulin for those patients with an A1c equal to or greater than 10%.**

DPP-4 inhibitor MNC requires failure of metformin plus at least one other generic oral antihyperglycemic agent (i.e. a sulfonylurea) when a patient’s Hgb A1c is below 10%. When a patient’s Hgb A1c is at least 10%, Neighborhood requires failure of an adequate dose and duration of basal insulin therapy. Coverage of DPP-4 inhibitors is dependent on the demonstration of adherence to current diabetes medications.

The American Diabetes Association continues to recommend metformin as the first-line pharmacologic agent for all diabetes mellitus type 2 patients, unless otherwise contraindicated. There have been limited trials comparing add-on therapy. A meta-analysis showed that each new class of a non-insulin agent added to therapy may lower a patient’s Hgb A1c by about 1%. Combination therapy of metformin with one other oral agent may be considered if the patient’s Hgb A1c is greater than 9%. Insulin should be considered when a patient’s blood glucose is greater than 300 to 350mg/dL and/or if the Hgb A1c is ≥10%. The DPP-4 inhibitor class has not been shown to provide improved clinical outcomes when compared to other oral anti-diabetes agents or insulin that may be added to metformin.

## SGLT2 Criteria & combination agents (all)
- Farxinga
- Invokana
- Invokamet
- Jardiance
- Xigduo XR

**Update SGLT2 inhibitor Medical Necessity Criteria (MNC) to require failure of insulin for those patients with an A1c equal to or greater than 10%.**

SGLT2 inhibitor MNC requires failure of metformin plus at least one other generic oral antihyperglycemic agent (i.e. a sulfonylurea) when a patient’s Hgb A1c is below 10%. When a patient’s Hgb A1c is at least 10%, Neighborhood requires failure of an adequate dose and duration of basal insulin therapy. Coverage of SGLT2 inhibitors is dependent on the demonstration of adherence to current diabetes medications.

The American Diabetes Association continues to recommend metformin as the first-line pharmacologic agent for all diabetes mellitus type 2 patients, unless otherwise contraindicated. There have been limited trials comparing add-on therapy. A meta-analysis showed that each new class of a non-insulin agent added to therapy may lower a patient’s Hgb A1c by about 1%. Combination therapy of metformin with one other oral agent may be considered if the patient’s Hgb A1c is greater than 9%. Insulin should be considered when a patient’s blood glucose is greater than 300 to 350mg/dL and/or if the Hgb A1c is ≥10%. The SGLT2 inhibitor class has not been shown to provide improved clinical outcomes when compared to other oral anti-diabetes agents or insulin that may be added to metformin.
### Thiazolidinediones & combination agents (all)
- Avandia
- metformin-pioglitazone

Update thiazolidinediones (TZD) Medical Necessity Criteria (MNC) to require failure of insulin for those patients with an Hgb A1c equal to or greater than 10%.

TZD MNC requires failure of metformin plus at least one other generic oral antihyperglycemic agent (i.e. sulfonylurea) and pioglitazone when a patient’s Hgb A1c is below 10%. When a patient’s Hgb A1c is at least 10%, Neighborhood requires failure of an adequate dose and duration of basal insulin therapy. Coverage of TZDs is dependent on the demonstration of adherence to current diabetes medications.

Pioglitazone is covered on Formulary without any restrictions.

The American Diabetes Association continues to recommend metformin as the first-line pharmacologic agent for all diabetes mellitus type 2 patients, unless otherwise contraindicated. There have been limited trials comparing add-on therapy. A meta-analysis showed that each new class of a non-insulin agent added to therapy may lower a patient’s Hgb A1c by about 1%. Combination therapy of metformin with one other oral agent may be considered if the patient’s Hgb A1c is greater than 9%. Insulin should be considered when a patient’s blood glucose is greater than 300 to 350mg/dL and/or if the Hgb A1c is ≥10%. The thiazolidinediones (TZD) class has not been shown to provide improved clinical outcomes when compared to other oral anti-diabetes agents or that may be added to metformin.

### GLP-1 Agonists
- Byetta
- Bydureon
- Victoza
- Tanzeum
- Trulicity

Update GLP-1 agonist Medical Necessity Criteria (MNC) to require failure of insulin therapy.

GLP-1 agonist MNC requires failure of metformin, a sulfonylurea and insulin therapy. Coverage of GLP-1 agonists is dependent on the demonstration of adherence to current diabetes medications.

The American Diabetes Association continues to recommend metformin as the first-line pharmacologic agent for all diabetes mellitus type 2 patients, unless otherwise contraindicated. There have been limited trials comparing add-on therapy. Insulin should be considered when a patient’s blood glucose is greater than 300 to 350mg/dL and/or if the Hgb A1c is ≥10%. The GLP-1 agonist class has not been shown to provide improved clinical outcomes when compared to other oral anti-diabetes agents or that may be added to metformin.

### Modafinil

Update modafinil Medical Necessity Criteria (MNC) to require failure of methylphenidate CD and at least one amphetamine product.

Modafinil MNC requires that a patient is being treated for narcolepsy, obstructive sleep apnea syndrome (OSAS) or shift work sleep disorder (SWSD); and has failed methylphenidate CD and at least one amphetamine product, unless otherwise contraindicated.

Modafinil does not provide a clinical advantage over Formulary stimulants. This updated criteria to require failure of methylphenidate CD is aligned with criteria for non-Formulary stimulants. Modafinil is significantly more expensive than Formulary alternatives.

Modafinil is covered through the Prior Authorization process.
### Non-Stimulant ADHD Agents
- Strattera
- Guanfacine ER

Update non-stimulant attention deficit/hyperactivity disorder (ADHD) agents (i.e. Strattera) Medical Necessity Criteria (MNC) to require failure of methylphenidate CD and at least one amphetamine product, unless otherwise contraindicated.

MNC requires that a patient has failed methylphenidate CD and at least one amphetamine product. For guanfacine extended-release (Intuniv ER), a patient is required to fail guanfacine immediate-release tablet prior to coverage of the extended-release tablet.

Updated MNC for non-stimulant ADHD agents is aligned with criteria for non-Formulary stimulants (e.g. dexamethylphenidate, Vyvanse). Non-Stimulant ADHD agents, such as Strattera, have not been shown to provide a clinical advantage compared to Formulary alternatives. Non-Stimulant ADHD agents are suitable alternatives for those who have either failed, or who have a contraindication to Formulary alternatives and continue to require ADHD therapy. Non-Stimulant ADHD agents are significantly more expensive than Formulary alternatives. Non-Stimulant ADHD agents are covered through the Prior Authorization process.

### Antispasmodic & Anticholinergic Agents
- Chlordiazepoxide-clidinium
- Myrbetriq

Remove chlordiazepoxide-clidinium from Formulary.

Update Myrbetriq Medical Necessity Criteria to include the requirement of failure of over-the-counter (OTC) Oxytrol Patch. Myrbetriq MNC requires failure of oxybutynin immediate-release tablet/syrup, over-the-counter (OTC) Oxytrol Patch, oxybutynin extended-release tablet and trospium immediate-release tablet.

Chlordiazepoxide-clidinium is a Drug Efficacy Study Implementation (DESI) drug. DESI drugs entered the market between 1938 and 1962, during a time at which drugs were only evaluated for safety and not effectiveness. Treatment alternatives available on Formulary include dicyclomine, hyoscyamine and loperamide.

Myrbetriq has not been shown to provide a clinical advantage over available Formulary alternatives. Myrbetriq is significantly more expensive then Formulary alternatives. Myrbetriq is covered through the Prior Authorization process.

### Enzymes
- Granulex
- Vasolex
- Santyl ointment
- Pancrealipase 5,000 unit capsule

Remove Granulex spray and Vasolex ointment from Formulary.

Do not add Santyl ointment to Formulary; create Medical Necessity Criteria (MNC).

Santyl MNC requires patients being treated for chronic dermal ulcers to fail hydrogel therapy in combination with surgical debridement; and patients being treated for severely burned areas to fail therapy with topical silver sulfadiazine.

Add pancrealipase (Zenpep®) 5,000 unit to Formulary, unrestricted.

Granulex spray and Vasolex ointment are both Drug Efficacy Study Implementation (DESI) drugs. DESI drugs entered the market between 1938 and 1962, during a time at which drugs were only evaluated for safety and not effectiveness.

Santyl ointment is indicated in the treatment of chronic dermal ulcers; and treatment of severely burned areas. Topical silver sulfadiazine is covered on the Neighborhood Formulary, unrestricted. Santyl ointment is covered through the Prior Authorization process.

Pancrealipase 5,000 unit capsule is the only strength of Zenpep® generically available and AB-rated. Pancrealipase 5,000 unit capsule is significantly less expensive than treatment alternatives. Alternatives do not provide a clinical advantage over pancrealipase.
**March 2015**

### Anti-Ulcer/Gastrointestinal Preps
- Nizatidine capsule
- First-Omeprazole liquid
- Prevacid SoluTab

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove nizatidine capsule from Formulary.</td>
</tr>
<tr>
<td>Update Prevacid Solutab Medical Necessity Criteria (MNC) to require failure of ranitidine liquid and First-Omeprazole 2mg/ml liquid.</td>
</tr>
<tr>
<td>Increase the age limit on First-Omeprazole 2mg/ml to allow all members who are ( \leq 10 ) years of age to have access to the medication without a prior authorization required.</td>
</tr>
</tbody>
</table>

Nizatidine is an H2 antagonist that does not provide a clinical advantage over Formulary alternatives. Ranitidine, famotidine and cimetidine are alternative H2 antagonists covered on Formulary without any restrictions. Nizatidine is more expensive than the above listed Formulary alternatives. Nizatidine is covered through the Prior Authorization process.

First-Omeprazole 2mg/ml liquid is an appropriate alternative for those pediatric patients who are \( \leq 10 \) years of age who require therapy with a liquid proton pump inhibitor (PPI) and who are unable to achieve an adequate clinical outcome with an H2 antagonist (i.e. ranitidine) or are unable to ingest the omeprazole capsules.

Ranitidine liquid may be used in infants and children; omeprazole is indicated for use in children who weigh \( \geq 5 \)kg. Prevacid Solutab does not provide a clinical advantage when compared to ranitidine or omeprazole. Omeprazole is the active ingredient in the First-Omeprazole kit. Prevacid Solutab is significantly more expensive than either ranitidine or First-Omeprazole liquid.

### Laxatives
- Movantik® (naloxegol)
- Relistor® (methylnaltrexone bromide)

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not add Movantik to Formulary; create Medical Necessity Criteria (MNC).</td>
</tr>
<tr>
<td>Movantik MNC requires that the patient is an adult being treated for opioid-induced constipation (OIC) who has been taking an opioid for at least 4 weeks for non-cancer pain; and has failed a recent trial of an appropriate dose and duration of polyethylene glycol plus at least one other laxative (e.g. lactulose, bisacodyl, senna); and that the patient does not have a known or suspected mechanical gastrointestinal (GI) obstruction. Docusate is not considered an acceptable alternative to a laxative.</td>
</tr>
</tbody>
</table>

Movantik is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Movantik works to decrease opioid constipating-effects directly in the GI tract by inhibiting peripheral opioid effects without impairing the pain killer effects of the drug. Movantik has not been shown to have a clinical advantage compared to Formulary alternatives, such as polyethylene glycol powder, lactulose, senna and/or bisacodyl. Movantik is not effective for use in patients with a mechanical GI obstruction. Movantik is significantly more expensive than Formulary alternatives. Movantik is not a member of a protected class. Movantik is covered through the Prior Authorization process.
| Laxatives (continued) | Do not add Relistor to Formulary; create Medical Necessity Criteria (MNC).

Relistor MNC for the treatment of opioid-induced constipation in an adult patient with an advanced illness receiving palliative care requires failure of a recent trial of an appropriate dose and duration of polyethylene glycol plus at least one other laxative (e.g. lactulose, bisacodyl, senna); and that there is no known or suspected mechanical gastrointestinal obstruction; and that the patient does not have a catheter in abdominal wall. Relistor is covered for non-cancer chronic pain in an adult patient being treated for opioid-induced constipation (OIC) who has been taking an opioid for at least 4 weeks for non-cancer pain; and has experienced less than 3 bowel movements (BMs) per week; and has failed a recent trial of appropriate dose and duration of polyethylene glycol plus at least one other laxative (e.g. lactulose, bisacodyl, senna); and patient has failed Movantik; and there is no known or suspected mechanical gastrointestinal obstruction; and patient does not have a catheter in abdominal wall.

| Entyvio® (vedolizumab) | Do not add Entyvio® to Formulary. Create Medical Necessity Criteria (MNC).

Entyvio MNC requires a diagnosis of moderately to severely active ulcerative colitis (UD) or Crohn’s disease (CD) and failure of at least one tumor necrosis factor (TNF) blocker. If criteria are met, initial approvals are given for 4 months. After four months of therapy, it is required that the patient’s clinical status be re-evaluated prior to submitting the request for continuation of Entyvio coverage. For the treatment of UC, clinical response status using the “Full” Mayo score is required after 4 months of therapy; and status clinical remission status is required at 12 months of therapy. For the treatment of CD, response to Entyvio using the Crohn’s Disease Activity Index (CDAI) score is required.

|  | Relistor is indicated in the treatment of opioid-induced constipation in adults with chronic non-cancer pain; and in adults who are receiving palliative care for an advanced illness (e.g. cancer). Relistor has not has not been shown to have a clinical advantage compared to Formulary alternatives, such as polyethylene glycol powder, lactulose, senna and/or bisacodyl. Relistor has not been shown to have a clinical advantage over Movantik. Movantik is an orally administered tablet which may provide easier to administer than Relistor for injection. Relistor is significantly more expensive than Formulary alternative and Movantik. Relistor is not a member of a protected class. Relistor is covered through the Prior Authorization process.

|  | Relistor is indicated in the treatment of adults with moderately to severely active ulcerative colitis (UC) following failure of treatment alternatives (e.g. TNF blockers, immunomodulators) for inducing and maintaining clinical response and clinical remission; and improving endoscopic appearance of the mucosa; and achieving corticosteroid-free remission. Entyvio is also indicated in the treatment of adults with moderately to severely active Crohn’s disease following failure of treatment alternatives (e.g. TNF blockers, immunomodulators) for inducing and maintaining clinical response and clinical remission; and achieving corticosteroid-free remission. Entyvio does not provide a clinical advantage over available Formulary alternatives (e.g. Humira, Remicade). Entyvio is not a member of a protected class. Entyvio is covered through the Prior Authorization process.
### DESI Drugs
- Hydrocortisone 25mg suppository
- Guaifenesin DAC syrup
- Hydrocortisone-pramoxine 2.5%-1% cream
- Hydrocortisone-pramoxine 1%-1% cream
- Isomethptene-dichloralphenazone-acetaminophen
- Estrogen-methyltestosterone H.S. tablet
- Estrogen-methyltestosterone tablet

Implement a quantity limit of 12 hydrocortisone 25mg supp/Rx. Limit 2 Rxs/month.

Remove guaifenesin DAC syrup from Formulary.

Implement a quantity limit on Hydrocortisone-pramoxine 2.5%-1% cream of 30 grams/Rx.

Remove hydrocortisone-pramoxine 1%-1% cream from Formulary; require Prior Authorization.

Remove isomethptene-dichloralphenazone-acetaminophen from Formulary.

Remove estrogen-methyltestosterone H.S. and regular strength tablets from Formulary.

### Diabetic Test Strips
Reduce the allowable quantity limit on diabetes test strips to the following:
- 25 strips per 25 days for non-insulin dependent patients who are ≥18 years old;
- 100 test strips per 25 days for insulin dependent patients who are ≥18 years old;
- 100 test strips per prescription fill and up to 2 fills per month for insulin dependent patients who are ≤18 years old;
- 100 test strips per prescription fill and up to 2 fills per month for insulin dependent female patients aged 15 to 44 years being treated for gestational diabetes.

### Drug Efficacy Study Implementation (DESI)
Drug entered the market between 1938 and 1962, during a time at which drugs were only evaluated for safety and not effectiveness. For select DESI drugs, there are limited treatment alternatives available. DESI drugs with limited alternatives will remain on the Neighborhood Formulary; quantity limits will promote appropriate utilization of the agent(s).

DESI drugs with treatment alternatives will be removed from the Formulary as multiple alternatives are available and covered by Neighborhood. Alternatives to guaifenesin DAC include guaifenesin AC, dextromethorphan and guaifenesin DM. Hydrocortisone-pramoxine 2.5%-1% cream is an alternative to hydrocortisone-pramoxine 1%-1% cream. Alternative migraine and headache relief therapies include triptans (e.g. sumatriptan, rizatriptan, and naratriptan), oral NSAIDs (e.g. naproxen, meloxicam, and ibuprofen) and butalbital-containing preparations (e.g. butal-apap-caff).

Recommended allowable quantity limits on diabetes test strips are aligned with ADA recommendations for patients self-monitoring of glucose levels. Patients who are insulin dependent; newly diagnosed; or treated for gestational diabetes may require additional testing strips for self-monitoring of glucose levels. Coverage of quantities above the allowable quantity limit may be requested through the Prior Authorization process.
| Prednisolone acetate ophthalmic solution | Add prednisolone acetate 1% ophthalmic solution to Formulary; implement a quantity restriction of 5ml per prescriptions; allow up to three prescriptions per year. | Prednisolone acetate ophthalmic solution was previously removed from the Formulary following the June 2014 P&T Committee meeting. The Formulary change is a reversal of the June 2014 Committee decision due to the drug’s preferred choice for eye-surgery and other select ocular conditions (e.g., uveitis). The purpose of implementing a quantity limit on the drug is to promote appropriate utilization. Coverage of quantities above the allowable quantity limit may be requested through the Prior Authorization process. |

**Please call the Pharmacy Help Desk at 1-401-459-6020 for pharmacy authorization requests or for further information on the Neighborhood formulary.**

**Explanation of Terms**

Products listed as “added” are available to most Neighborhood members at zero copay; if restrictions apply they will be indicated on this form and in the electronic formulary. Drugs may be limited to certain age groups (an AGE EDIT), by demonstrating prior therapies have been attempted (a STEP EDIT), in quantity allowed per 30 days (a QUANTITY LIMIT), or by requiring precertification for use from NHPRI (a PRIOR AUTHORIZATION). Products listed as “removed” are no longer available to Neighborhood members and are considered non-formulary or benefit exclusions. Physicians may requests these products via the medical necessity request process only.