

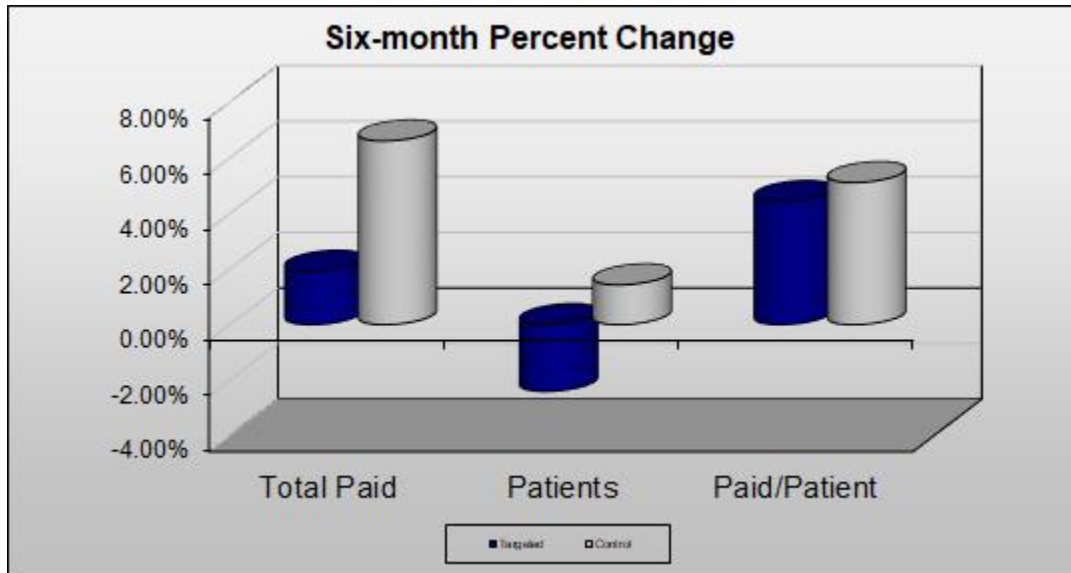
## Combined Use of Opioids and Central Nervous System (CNS) Depressants Drug Use Evaluation

Prepared for Texas Medicaid in February 2023

### EXECUTIVE SUMMARY

Purpose of Intervention	This intervention is designed to improve the management of patients on potentially harmful combinations of opioids and various CNS depressants (i.e., benzodiazepines, antipsychotics, muscle relaxants, sedative hypnotics, and gabapentinoids).
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Intervention	Intervention Type	Population-based mailing
	Intervention Mailing Date	April 8, 2022
	Pre-intervention Period (Pre)	October 2021 – March 2022
	Post-intervention Period (Post)	May 2022 – October 2022
	Number of Letters Mailed	45
	Number of Targeted Physicians	46



### SAVINGS CALCULATION

State Cost Savings Calculation:	
Targeted Group: Actual Opioid and CNS Depressant Drugs Average Cost Per Patient Per Month (Pre)	\$135.71
% Change in Control Group from Pre to Post	5.11%
Estimated Opioid and CNS Depressant Drugs Paid Amount Per Targeted Patient Per Month if No Intervention	\$142.64
Targeted Group: Opioid and CNS Depressant Drugs Cost Per Patient Per Month (Post)	\$141.72
Estimated Cost Savings Per Patient Per Month	\$0.92
Total Number of Targeted Panel Patients Served in Post Period	8,292
<b>6-Month Total Savings</b>	<b>\$7,628.64</b>
<b>6-Month State General Revenue Funds Savings</b>	<b>\$3,052.22</b>
<b>12-Month Total State Savings</b>	<b>\$6,104.44</b>

## BACKGROUND

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The prescribing of opioids should be based on careful consideration of benefits and risks associated with their use. Serious risks of opioid pain medications include opioid use disorder, overdose, and death. Medical professionals are advised to help mitigate these risks by evaluating the use of all central nervous system (CNS) agents while paying special attention to medications likely to cause sedation or respiratory depression.<sup>1</sup>

CNS depressants include medications such as benzodiazepines, antipsychotics, muscle relaxants, sedative hypnotics, and gabapentinoids (i.e., pregabalin and gabapentin). Drug classes like benzodiazepines, when combined with opioids, have resulted in such serious adverse effects, including death, that the U.S. Food and Drug Administration (FDA) issued its strongest warning against their combined use.<sup>2</sup> The FDA also required an updated Boxed Warning for all benzodiazepines regarding the risks of abuse, addiction, physical dependence, and withdrawal reactions.<sup>3</sup>

Similarly, The Centers for Medicare & Medicaid Services (CMS) provided guidance on risks associated with opioids in H.R.6 section 1004, more commonly known as the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.<sup>4</sup> The recommendations are geared toward increasing patient safety by requiring states to have an automated review process in place that monitors patients concurrently prescribed opioids, benzodiazepines and other CNS depressants, and/or antipsychotics.<sup>4</sup>

### Indicator #1: Use of opioid analgesics in combination with benzodiazepines

Combining an opioid analgesic with benzodiazepines greatly increases the risk of serious side effects including extreme sleepiness, respiratory depression, overdose, and even death.<sup>1-6</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: medication-assisted treatment (MAT) drugs (Appendix B).

Exception Criteria (numerator): Candidates with 14 days or more of overlapping benzodiazepine (Appendix C) therapy in the past 35 days. Excluded: patients with cancer, sickle cell disease or a hospice designation in the past 730 days.

### Indicator #2: Use of opioid analgesics in combination with antipsychotics

Combining an opioid analgesic with an antipsychotic increases the risk of serious side effects including extreme sleepiness, respiratory depression, and even death. Patients with mental health conditions also have a higher probability of experiencing opioid-related harms. This can be due to concomitant medication use (i.e., antipsychotics, benzodiazepines, and other CNS depressants), comorbidities such as alcohol or substance abuse, and the increased risk of opioid misuse in this population leading to overdose or addiction.<sup>1,4,5</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: MAT drugs (Appendix B).

Exception Criteria (numerator): Candidates with 14 days or more of overlapping antipsychotic (Appendix D) therapy in the past 35 days. Excluded: patients

with cancer, sickle cell disease or a hospice designation in the past 730 days.

**Indicator #3: Use of opioid analgesics in combination with benzodiazepines and antipsychotics**

Combining an opioid analgesic with benzodiazepines and antipsychotics greatly increases the risk of serious side effects including extreme sleepiness, respiratory depression, overdose, and even death. Coordination of care should be used to improve the treatment of co-morbid mental health disorders while being cognizant of the high rate of opioid use disorder in this population.<sup>1-7</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: MAT drugs (Appendix B).

Exception Criteria (numerator): Candidates with 14 days or more of overlapping benzodiazepine (Appendix C) and antipsychotic (Appendix D) therapy in the past 35 days. Excluded: patients with cancer, sickle cell disease or a hospice designation in the past 730 days.

**Indicator #4: Use of opioid analgesics in combination with muscle relaxants**

Combining opioid analgesics with muscle relaxants has been shown to increase the risk of overdose due to additive respiratory and central nervous system depression.<sup>1,4-6</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: MAT drugs (Appendix B).

Exception Criteria (numerator): Candidates with 14 days or more of overlapping muscle relaxant (Appendix E) therapy in the last 35 days. Excluded: patients with cancer, sickle cell disease or a hospice designation in the past 730 days.

**Indicator #5: Use of opioid analgesics in combination with benzodiazepines and muscle relaxants**

Combining opioid analgesics with muscle relaxants and benzodiazepines has been shown to increase the risk of overdose due to additive respiratory and central nervous system depression.<sup>1-6</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: MAT drugs (Appendix B).

Exception Criteria (numerator): Candidates with 14 days or more of overlapping muscle relaxant (Appendix E) and benzodiazepine (Appendix C) therapy in the last 35 days. Excluded: patients with cancer, sickle cell disease or a hospice designation in the past 730 days.

**Indicator #6: Use of opioid analgesics in combination with sedative hypnotics**

Combining opioid analgesics with sedative hypnotics has been shown to increase the risk of overdose due to additive respiratory and central nervous system depression.<sup>1-6</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: MAT drugs (Appendix B).

Exception Criteria (numerator): Candidates with 14 days or more of overlapping sedative hypnotic (Appendix F, select agents) therapy in the last 35 days. Excluded: patients with cancer, sickle cell disease or a hospice designation in the past 730 days.

**Indicator #7: Use of opioid analgesics in combination with benzodiazepines, sedative hypnotics or gabapentinoids without naloxone**

The risk of opioid overdose increases in patients who use opioids concurrently with benzodiazepines, sedative hypnotics or gabapentinoids. Concomitant use of opioids with other CNS depressants increases the risk of respiratory depression, coma, and even death. The CDC and FDA recommend offering naloxone to those at risk of overdose.<sup>1-7</sup>

Candidates (denominator): Patients with opioid (Appendix A) analgesic therapy in the past 30 days. Excluded: MAT drugs (Appendix B).

Exception Criteria (numerator): Candidates with greater than 14 days of overlapping benzodiazepine (Appendix C), sedative hypnotic (Appendix F) or gabapentinoid (Appendix G) therapy in the past 35 days and no history of naloxone therapy in the past 730 days.

**METHODOLOGY**

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In April 2022, all physicians treating patients with any of the aforementioned drug-related problems were identified. Based on the distribution of patients/physician, the minimum patient/month threshold was set at one or more patients (i.e., physicians with one or more patients having a drug-related problem received the mailing). Providers were mailed the intervention materials on April 8, 2022.

Operational definitions:

**Targeted Group** – physicians treating one or more patients with any of the aforementioned drug-related problem(s) and who received mailed intervention materials (*Section 1.e.1.A Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal*).

**Control Group** - physicians treating patients taking opioids with other CNS depressant drugs but did not receive mailed intervention materials (*Section 1.e.1.A Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal*).

**Intervention Drugs** – Opioid Analgesics, CNS Depressant drugs, and Naloxone

**Pre-Intervention Time Period** – October 2021 through March 2022

**Post-Intervention Time Period** – May 2022 through October 2022

**6-month Total Paid** – total drug costs can be defined as the total amount of paid intervention drug claims for the above time periods for the prescribers in the control and target groups. The target group consisted of those prescribers who had prescribed intervention drug therapy to Medicaid patients and received intervention materials. The control group consisted of all other prescribers who prescribed opioid analgesics with other CNS depressant drug therapy agents in the designated time periods (*Sections 1.e.1. and 1.e.2 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal*).

**Average Number of Panel Patients per Month** - during the 6-month pre and post time periods, the number of unique Medicaid patients with a drug claim submitted using a respective provider number was captured each month. Medicaid patients that did not have a drug claim were not counted in the prescriber’s panel. The monthly numbers were totaled then divided by six to calculate the monthly average. For example, in Table 1, the physician (with provider number AB123456) had an average of 12 patients with at least one drug claim per month. If a patient had two different claims in June, they would be counted as one patient. By evaluating all patients seen by a specific physician, changes in prescribing patterns can be evaluated on existing and new patients (*Sections 1.e.1. and 1.e.2 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal*).

**Table 1: Average Number of Panel Patients per Month**

Provider Number	Month #	Number of Unique Patients with a Drug Claim
AB123456	1	10
	2	10
	3	10
	4	12
	5	13
	6	17
<b>Total</b>		<b>72</b>
<b>Average Number of Panel Patients per Month</b>		<b>12</b>

**Average Cost/Patient per Month** – this was calculated by dividing the total dollars paid for drug claims during the analysis time period by the total number of Medicaid panel patients during the respective time period. For example, in the targeted group post analysis; there were 8,292 patients who had an intervention drug claim during the six-month review period, for an average of 1,382 panel patients per month. The total amount of dollars paid for drug claims for these patients during the post analysis was \$1,175,172. Dividing these two numbers [ $\$1,175,172 / (1,382 \times 6)$ ] yields an average cost per patient of \$141.72 (*Sections 1.e.1. and 1.e.2 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal*).

$$\text{Average Cost/Patient/per Month} = \frac{\text{6-month Total Amount Paid for Intervention Drugs}}{\text{Average number of Panel Patients per Month}} / (\# \text{ Months})$$

**Total State Savings** (Sections 1.e.3 and 1.e.4 Exhibit A of the Agreed Modifications to the RFP and Contractor Proposal):

- Intervention Average Cost Savings per Month – the percent change seen in the control group was applied to the intervention group baseline Average Cost per Patient per Month. This amount represents the estimated Amount Paid per Targeted Physician per Patient in the absence of the intervention (i.e., Estimated Paid Amount). The Estimated Paid Amount per Patient per Month was then subtracted from the actual Intervention Target Group Average Cost per Patient per Month to estimate the Average Cost Savings per Patient per Month.
- 6-Month Total Savings – the Intervention Average Cost Savings per Patient per Month was multiplied by the total number of targeted patients served over the 6-month time frame.
- 6-Month State General Revenue Funds Savings= 6-Month Total State Savings X 0.4001.
- Total State Savings = 6-Month State General Revenue Funds Savings X 2.

## RESULTS

### Population-based intervention

A total of 46 physicians were targeted, and one letter was removed due to an incomplete address. A total of 45 physicians received intervention materials. Table 2 compares the 6-month total amount paid for intervention drugs opioid analgesics, CNS depressant drugs, and naloxone, the total number of patients in each physician’s panel per month, and the average cost per patient for the targeted and control groups during the six-month pre and post periods. When comparing the pre-Average Cost per Patient per Month between the targeted and control groups, the cost was approximately \$46 lower for the targeted group. This difference may be due to such factors as the control group having more patients prescribed opioid and CNS depressant drugs per physician or that associated average intervention-related drug costs are inherently lower in the targeted group.

The target group saw a 1.92% increase in the amount paid for intervention-related drugs while the control group saw a 6.61% increase. Additionally, the average number of monthly patients for the physician’s panel decreased 2.40% for the target group and increased 1.43% for the control group. To control for changes in case load variance (i.e., the change in the number of panel patients) between the two groups, the average cost per patient was also calculated. Total amount paid and number of panel patient trends led to a 4.43% increase in average cost per patient per month in the targeted group and a 5.11% increase for the control group.

**Table 2: Six-Month Trends for Overall Targeted vs Control Group**

Group	Opioid and CNS Depressant Drugs Six Months Total Paid Pre/Post			Average Number of Panel Patients per Month			Opioid and CNS Depressant Drugs Average Cost per Patient per Month		
	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change
Targeted	\$1,153,011	\$1,175,172	1.92%	1,416	1,382	-2.40%	\$135.71	\$141.72	4.43%
Control	\$202,256,052	\$215,621,948	6.61%	185,489	188,136	1.43%	\$181.73	\$191.02	5.11%

Table 3 shows the Intervention Average Cost Savings per Patient per Month and the savings calculations. Had the intervention not been mailed, the targeted pre average cost per patient per month would have increased 5.11% from \$135.71 to \$142.64. The net difference between the actual and estimated average cost/patient for the targeted group was \$0.92. Based on 8,292 targeted patients served during the six-month post period, the six-month Total Savings and



Total State Savings were \$7,628.64 and \$3,052.22 respectively. Over a twelve-month period, the Total State Savings was \$6,108.44.

**Table 3: Overall Intervention Average Cost Savings**

<b>State Cost Savings Calculation:</b>	
Targeted Group: Actual Opioid and CNS Depressant Drugs Average Cost Per Patient Per Month (Pre)	\$135.71
% Change in Control Group from Pre to Post	5.11%
Estimated Opioid and CNS Depressant Drugs Paid Amount Per Targeted Patient Per Month if No Intervention	\$142.64
Targeted Group: Opioid and CNS Depressant Drugs Cost Per Patient Per Month (Post)	\$141.72
Estimated Cost Savings Per Patient Per Month	\$0.92
Total Number of Targeted Panel Patients Served in Post Period	8,292
6-Month Total Savings	\$7,628.64
6-Month State General Revenue Funds Savings	\$3,052.22
12-Month Total State Savings	\$6,104.44

Table 4 shows the changes in the clinical indicators based on the intervention. The overall change in indicators is a decrease of 33.3%.

**Table 4: Overall Intervention Changes in Clinical Indicators**

<b>Clinical Indicators</b>			
	<b>Baseline</b>	<b>Oct-2022</b>	<b>% Change</b>
Use of opioid analgesics in combination with benzodiazepines	7	5	-28.6%
Use of opioid analgesics in combination with antipsychotics	2	1	-50.0%
Use of opioid analgesics in combination with benzodiazepines and antipsychotics	3	2	-33.3%
Use of opioid analgesics in combination with muscle relaxants	1	1	0.0%
Use of opioid analgesics in combination with benzodiazepines and muscle relaxants	2	1	-50.0%
Use of opioid analgesics in combination with sedative hypnotics	0	0	0.0%
Use of opioid analgesics in combination with benzodiazepines, sedative hypnotics or gabapentinoids without naloxone	33	22	-33.3%
Total	48	32	-33.3%

## CONCLUSIONS

This population-based intervention was successful in encouraging appropriate use of combined opioid and CNS depressant drug therapy and providing prescribers with educational tools to better communicate with their patients' issues regarding appropriate treatment. This resulted in an economic impact on Texas Medicaid's pharmacy program expenditures, with a calculated twelve-month overall savings of \$15,257.28 and savings to the State of \$6,104.44 and a decrease in clinical indicators of 33.3%.

## REFERENCES

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6. FDA Drug Safety Communication: FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder. July 23, 2020. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-health-care-professionals-discuss-naloxone-all-patients-when-prescribing-opioid-pain>. Accessed 8/2021.
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## Appendices:

Appendix A – Opioid Analgesics	
Specific Therapeutic Category (STC)	STC Description
H3A	OPIOID ANALGESICS
H3M	OPIOID, NON-SALICYL ANALGESIC, BARBITURATE, XANTHINE
H3N	OPIOID ANALGESIC AND NSAID COMBINATION
H3R	OPIOID AND SALICYLATE ANALGESICS, BARBIT, XANTHINE
H3U	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS
H3X	OPIOID ANALGESIC AND SALICYLATE ANALGESIC COMB
H3Z	OPIOID ANALGESIC, NON-SALICYLATE, XANTHINE COMB
S7G	SKELETAL MUSCLE RELAXANT, SALICYLATE, OPIOID ANALGESIC

Appendix B – Medication-Assisted Treatments (MAT)	
Generic Code Number (GCN)	GCN Description
44187	BUPRENORPHINE 100 MG/0.5 SOLER SYR SUBCUT



Appendix B – Medication-Assisted Treatments (MAT)	
44186	BUPRENORPHINE 300 MG/1.5 SOLER SYR SUBCUT
64672	BUPRENORPHINE HCL 2 MG TAB SUBLINGUAL
41432	BUPRENORPHINE HCL 74.2 MG IMPLANT
64673	BUPRENORPHINE HCL 8 MG TAB SUBLINGUAL
42843	BUPRENORPHINE HCL/NALOXONE HCL 0.7-0.18MG TAB SUBLINGUAL
34904	BUPRENORPHINE HCL/NALOXONE HCL 1.4-0.36MG TAB SUBLINGUAL
37824	BUPRENORPHINE HCL/NALOXONE HCL 11.4-2.9MG TAB SUBLINGUAL
33744	BUPRENORPHINE HCL/NALOXONE HCL 12 MG-3 MG FILM SUBLINGUAL
28958	BUPRENORPHINE HCL/NALOXONE HCL 2 MG-0.5MG FILM SUBLINGUAL
18973	BUPRENORPHINE HCL/NALOXONE HCL 2 MG-0.5MG TAB SUBLINGUAL
36677	BUPRENORPHINE HCL/NALOXONE HCL 2.1-0.3 MG FILM BUCCAL
39394	BUPRENORPHINE HCL/NALOXONE HCL 2.9-0.71MG TAB SUBLINGUAL
36678	BUPRENORPHINE HCL/NALOXONE HCL 4.2-0.7 MG FILM BUCCAL
33741	BUPRENORPHINE HCL/NALOXONE HCL 4MG-1MG FILM SUBLINGUAL
34905	BUPRENORPHINE HCL/NALOXONE HCL 5.7-1.4 MG TAB SUBLINGUAL
36679	BUPRENORPHINE HCL/NALOXONE HCL 6.3MG-1MG FILM BUCCAL
28959	BUPRENORPHINE HCL/NALOXONE HCL 8 MG-2 MG FILM SUBLINGUAL
18974	BUPRENORPHINE HCL/NALOXONE HCL 8 MG-2 MG TAB SUBLINGUAL
37823	BUPRENORPHINE HCL/NALOXONE HCL 8.6-2.1 MG TAB SUBLINGUAL
52540	LOFEXIDINE HCL 0.18 MG TABLET ORAL
27095	NALTREXONE MICROSPHERES 380 MG SUS ER REC INTRAMUSC

Appendix C – Benzodiazepines	
STC	STC Description
H20	ANTI-ANXIETY - BENZODIAZEPINES
H21	SEDATIVE-HYPNOTICS – BENZODIAZEPINES
H2X	TRICYCLIC ANTIDEPRESSANT-BENZODIAZEPINE COMBINATIONS
H4A	ANTICONVULSANT - BENZODIAZEPINE TYPE

Appendix D – Antipsychotics	
H2G	ANTIPSYCHOTICS, PHENOTHIAZINES
H7O	ANTIPSYCHOTICS, DOPAMINE ANTAGONISTS, BUTYROPHENONES
H7P	ANTIPSYCHOTICS, DOPAMINE ANTAGONISTS, THIOXANTHENES
H7S	ANTIPSYCHOTICS, DOPAMINE ANTAGONST, DIHYDROINDOLONES
H7T	ANTIPSYCHOTIC, ATYPICAL, DOPAMINE, SEROTONIN ANTAGNST
H7U	ANTIPSYCHOTICS, DOPAMINE AND SEROTONIN ANTAGONISTS
H7X	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED
H7Z	SSRI-ANTIPSYCH, ATYPICAL, DOPAMINE, SEROTONIN ANTAG
H8W	ANTIPSYCHOTIC-ATYPICAL, D3/D2 PARTIAL AG-5HT MIXED

Appendix E – Muscle Relaxants	
Hierarchical Ingredient Code (HIC)	HIC Description
001949	BACLOFEN
001944	CARISOPRODOL
001942	CARISOPRODOL/ASPIRIN
001720	CARISOPRODOL/ASPIRIN/CODEINE
001941	CHLORZOXAZONE
047065	CYCLOBENZAP/LIDO/PRILOC/GLYCER
001950	CYCLOBENZAPRINE HCL
035728	CYCLOBENZAPRINE/IRR CNTR-IRR 2
046613	CYCLOBENZAPRINE/LIDOCAIN/MENTH
044514	CYCLOBENZAPRINE/TENS ELECTRODE
044513	CYCLOBENZAPRINE/TENS UNIT/ELEC
001947	DANTROLENE SODIUM
001945	METAXALONE
001938	METHOCARBAMOL
001906	ORPHENADRINE CITRATE

Appendix E – Muscle Relaxants	
001791	ORPHENADRINE/ASPIRIN/CAFFEINE
011582	TIZANIDINE HCL
036990	TIZANIDINE/IRRITANT CNTR-IRRT2

Appendix F – Sedative Hypnotics	
STC	STC Description
H2E	SEDATIVE-HYPNOTICS, NON-BARBITURATE
H7W	ANTI-NARCOLEPSY, ANTI-CATAPLEXY, SEDATIVE-TYPE AGENT

Appendix G – Gabapentinoids	
HIC	HIC Description
008831	GABAPENTIN
037574	GABAPENTIN ENACARBIL
046213	GABAPENTIN/LIDOCAINE
046682	GABAPEN/LIDOCAINE/GAUZE/SILCON
043174	GABAPENTIN/LIDOCAINE/MENTHOL
046643	GABAPENTIN/LIDOCAINE/SILICONE
026470	PREGABALIN