INDIAN HEALTH SERVICE
National Pharmacy and Therapeutics Committee
Formulary Brief: ***Low Back Pain***
-January 2024-

Background:

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) provided a drug class review of low back pain agents. This marks the first NPTC review of medications specific to this condition. Medications listed on the IHS National Core Formulary (NCF) relevant to this condition include acetaminophen, aspirin, buprenorphine, diclofenac, duloxetine, ibuprofen, indomethacin, meloxicam, naproxen and salsalate. Following clinical review and analysis, the NPTC **made no modifications** to the NCF.

Discussion:

Low back pain (LBP) is defined as pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds with or without leg symptoms.[1] It is further defined as acute, subacute (4 to 12 weeks) and chronic (>12 weeks). Over 85% of LBP is non-specific where no identifiable disease or structural reason is found. Serious etiologies such as cauda equina, metastatic cancer and spinal infection account for less than 1% of LBP, and less serious etiologies such as vertebral compression fracture, radiculopathy and spinal stenosis account for less than 10%.[2] An estimated 84% of adults experience LBP.

Back pain prevalence in a 2002 U.S. national survey noted that American Indian/Alaska Native people had the highest rate at 35.0%.[3] Approximately one-third of patients with acute low back pain (aLBP) seek medical care. Fortunately, 70-90% of patients improve within 7 weeks. However, 5-20% will develop chronic low back pain (cLBP) within the next 2 years.[4] Risk factors for developing cLBP include smoking, obesity, age, female sex, physically or psychologically strenuous work, sedentary work, somatization disorder, anxiety and depression.

Initial evaluation of patients with LBP includes a history to identify red flags such as cancer, unexplained weight loss, immunosuppression, intravenous drug use, fever, infections and significant trauma relative to their age. Examination of the spine and a thorough neurologic exam is performed. Red flags include saddle anesthesia, loss of anal sphincter tone, bladder or bowel incontinence, or major motor weakness in the lower extremities, and necessitate further work up, which may include labs and imaging.[5] Follow up evaluation usually occurs 4-6 weeks after conservative therapy and at that time, most patients with persistent LBP without warning signs or specific back pain continue with conservative treatment.

Goals for treatment are to decrease pain and to maintain function. Non-pharmacologic therapies are the mainstay for LBP treatment. They include heat, self-care, exercise therapy, massage, acupuncture, cognitive behavioral therapy (CBT) and mind-body interventions. Medications commonly used include NSAIDs, acetaminophen (APAP), muscle relaxants, steroids, opioids, antidepressants, anticonvulsants including gabapentinoids, and topical medications.

Several clinical practice guidelines for LBP were reviewed. All guidelines recommend non-pharmacologic interventions as first line therapy with medications second line.

- The 2017 American College of Physicians guidelines recommend heat for aLBP and subacute low back pain (sLBP), and to consider massage, acupuncture, and spinal manipulation.[6] If medication is desired, an NSAID or muscle relaxant can be offered. For cLBP, exercise, multidisciplinary rehab, acupuncture or mindfulness-based stress reduction (MBSR) are recommended with other adjunctive non-pharmacologic interventions to be considered. For inadequate response to these interventions, consider NSAIDs with tramadol and then duloxetine as second-line therapy. Only consider other opioids as an option in patients who failed the above treatments and only if benefits outweigh known risk and realistic benefits.
- The 2020 National Institute of Health and Care Excellent medication guidelines recommend considering NSAIDs after assessing toxicity and the person's risk factors including age, and to offer the medication at the lowest effective dose and frequency.[7] Consider weak opioids (with or without APAP) only if NSAIDs are contraindicated. Do not offer APAP alone, do not routinely offer opioids for managing aLBP, do not offer opioids for cLBP, do not offer selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors (SNRI), or tricyclic antidepressants for LBP, and do not offer gabapentinoids or antiepileptics for LBP.
- The North American Spine Society 2020 guidelines state non-selective NSAIDs are suggested in the treatment of LBP, antidepressants are not recommended, steroids are not effective, opioids should be limited and restricted to short duration, and topical capsicum is recommended as effective on a short-term basis (<3 months).[5]
- The VA/DoD 2022 guidelines suggest duloxetine for cLBP, suggest NSAID for LBP, recommend against muscle relaxants in cLBP, suggest against APAP, opioids, and steroids in LBP, recommend against benzodiazepines in LBP, make no recommendation for or against muscle relaxants in aLBP, and make no recommendation for or against gabapentinoids, tricyclics, and topicals for LBP.[1]

The Cochrane Library has several systematic reviews of medication interventions for LBP noted below. NSAIDs for aLBP[8] compared to placebo using a visual analogue scale (VAS) of 0-100 demonstrate effective short-term (≤ 3 weeks) reduction in pain intensity (mean difference (MD) -7.29, 95% confidence interval (CI) -10.98 to -3.61) as well as in disability using the Roland Morris Disability Questionnaire scale (RMDQ) of 0-24 (MD -2.02, 95% CI -2.89 to -1.15). The magnitude of the effect is small and probably not clinically relevant. Importantly, there was no difference in adverse events using NSAIDs compared to placebo (relative risk (RR) 0.86, 95% CI 0.63 to 1.18), and there was no difference between selective and non-selective NSAIDs. For cLBP, there is also a difference favoring NSAIDs compared to placebo at > 3 months and 12 months post-intervention for reducing pain using VAS (MD -6.97, 95% CI -10.74 to -3.19) and disability using RMDQ (MD -0.85, 95% -1.30 to -0.40), but again the improvement is small and likely not clinically relevant.[9] As with aLBP, there was no evidence for increased risk of adverse events compared to placebo, and no difference between selective and non-selective NSAIDs.

Recent systematic reviews have demonstrated that there is no difference between APAP and placebo for reducing pain or disability, but there is an increased risk of adverse events (relative risk (RR) 1.07, 95% CI 0.86 to 1.33).[9] Muscle relaxants compared to placebo in aLBP provide better pain relief (RR 0.58, 95% 0.45 to 0.76), better physical function (RR 0.55, 95% CI 0.40 to 0.77) [9] but a higher chance of adverse events (RR 1.50, 95% CI 1.14 to 1.98).[10] There was no difference to placebo in the risk of adverse events when given for cLBP (RR 1.02, CI 0.67 to 1.57).[9]

Antidepressants (all types) compared to placebo showed no benefit for cLBP for reducing pain or disability.[9] A 2021 systematic review of SNRI medications showed that duloxetine provides meaningful benefits with cLBP (RR 1.25, 95% CI 1.13 to 1.38), but withdrawals due to adverse events were doubled vs. placebo (RR 2.02, 95% CI 1.06 to 3.87).[11] Anticonvulsants studied for LBP include gabapentinoids.[12] There is no evidence of any benefit for pain or function, and there is high quality evidence for adverse effects of gabapentinoids. Steroids show no benefit in non-specific aLBP.[13]

Opioids are frequently used in both aLBP and cLBP. In a recently published study, patients with neck or LBP for <12 weeks were randomized to receive NSAID and opiates, or NSAID and placebo. There was no difference in pain or disability, but the opioid group had more opioid related adverse events, and at 52 weeks, the placebo group had less pain than the opioid group.[14] Opioid use in cLBP reduces pain versus placebo but the improvement is small and there is increased risk for adverse events.[9]

Topical medications are often used for LBP. There is moderate quality evidence that capsicum plaster or cream reduces pain and improves function more than placebo in the short-term for cLBP, and may reduce pain more than placebo in aLBP.[15] Lidocaine appears no better than placebo in treating LBP but the patch itself has been shown to induce a potent placebo effect in a significant portion of cLBP patients.[16] Topical NSAIDs have not demonstrated efficacy in either aLBP or cLBP.[17]

Findings:

Low back pain is a common problem seen in primary care. Fortunately, most patients with aLBP and sLBP improve without any significant intervention. Avoiding bedrest, remaining physically active and using heat is generally the best initial approach. For those with moderate to severe pain and no contraindication, NSAIDs are the initial medication of choice. If not tolerated or ineffective, a short course of a muscle relaxant may be beneficial. Topical capsicum can be considered, and if an opioid is needed, it should be cautiously limited and restricted to a short duration. When treating cLBP, non-pharmacologic therapies are indicated. Exercise (if no disabling pain or functional impairment), formal physical therapy, CBT, MBSR, biofeedback and progressive relaxation can all be considered first line if available. Medications can include NSAIDs, unless they have already been tried without benefit, and at the lowest effective dose and frequency. Duloxetine can be considered as a next step. A weak opioid (such as tramadol) is generally preferred if stronger pain medicine is needed. While the risk for constipation and dependence with this opioid is lower than other opioids, it still has abuse potential, so a review for substance use disorder is required. It may also increase risk of serotonin syndrome and can lower a patient's seizure threshold. Only use opioids if the realistic benefits outweigh the known risks.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov . For more information about the NPTC, please visit the NPTC website.

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