

To _____ (Insurance Provider):

I, _____, M.D., attest that _____ is under my care for HIV disease. He has shown considerable loss of weight and lean body mass. Kotler showed that loss of lean body mass to 54 percent of normal predicts mortality in HIV disease.¹ Macallan showed that loss of lean body mass of as little as 5 percent is associated with increased morbidity in HIV disease.² Therefore preservation of lean body mass may be critically important for survival and for the overall health of HIV-positive people, in general.

I recommend that _____ receive anabolic steroid therapy consisting of a combination of 200 mg per week of nandrolone decanoate and 100 mg per week of testosterone cypionate.

As detailed below, nandrolone is an injectable anabolic steroid shown to be safe and effective for the treatment of HIV-related weight loss. It is also currently the most economical of all anabolic agents used in HIV disease-care. (See comparison table below.) When compared to Serostim human growth hormone, another treatment for wasting, the nandrolone/testosterone combination treatment regimen mentioned above will cost approximately \$224 per month compared to \$6000 for Serostim, and data suggests that the nandrolone/testosterone combination is more effective for weight gain. (See comparison table below.)

The combination of the anabolic steroid nandrolone with a replacement dose of testosterone is needed because all anabolic steroid use decreases endogenous testosterone production, rendering the patient hypogonadal. Data from Salvato suggests that combining testosterone with nandrolone produces an additive effect that optimally increases lean body mass.³ This combination has become a standard therapy at clinics in Los Angeles, San Francisco, Houston, Miami, New York, and many of other cities during the last ten years.

Please let me know if you need any more information to ensure that this patient gets the coverage needed for this critically important, cost-effective treatment that can ensure his overall well-being and longevity while living with this debilitating disease.

Do not hesitate to call me at _____ Thank you.

Sincerely,

1. Kotler DP, et al. Magnitude of body-cell-mass depletion and the timing of death from wasting in AIDS. *Am J Clin Nutr* (1989) 50:444-447.

2. Macallan DC. Wasting in HIV infection and AIDS. *J Nutr* (1999) 129(1S Suppl):238S-242S.

3. Salvato P, et al. Conference on Nutrition and HIV Infection Cannes, France (1997) April 23-24; Abstract No. 0-003.

Nandrolone Decanoate (Deca Durabolin) Studies for HIV Wasting

By Nelson Vergel and Michael Mooney

Nandrolone Decanoate

Dr. Julian Gold, et al. of Australia, reported in his 16-week study that even with very low dose nandrolone (100 mg every two weeks), lean body mass and quality-of-life improved significantly (6.6 lbs.) in wasting HIV patients with no negative effect on CD4 lymphocytes.⁴ Dr. Gold was a trailblazer, as his study included nutritional assessment and suggestions for a specific exercise protocol before anyone else had done this.

At the XI International AIDS Conference (Vancouver) Dr. Gary Bucher, of Chicago's Center for Special Immunology, presented his 12 week 73 patient placebo-controlled study of the anabolic steroid nandrolone decanoate (Deca Durabolin) used at 100 mg per week.⁵ Nandrolone caused a 6 pound lean body mass increase and a 153 point average increase in CD8+ T cells, which have been associated with improved long-term survival.⁶

At the Bethesda NIH Conference on May 20, 1997, Dr. Marc Hellerstein said that about 50 percent of his HIV patients in San Francisco don't produce adequate testosterone. His team concluded a study that employed nandrolone decanoate and showed an 11.88 pound increase in lean body mass over 12 weeks. Nandrolone decreased lipogenesis significantly (nutrients tended to contribute to lean tissue more than to fat tissue). Improvements in strength, endurance, and quality-of-life paralleled body composition changes.⁷

A non-placebo-controlled, randomized study by Fred Sattler, M.D. was conducted to test the hypotheses that pharmacological doses of nandrolone decanoate would increase lean body tissue, muscle mass, and strength in HIV-positive men without exercise, and that these effects would be enhanced with progressive resistance weight training. Thirty HIV-positive men with fewer than 400 CD4+ lymphocytes/mm³ were randomly assigned to receive weekly injections of 600 mg/week of nandrolone alone or in combination with supervised resistance weight training at 80 percent of one repetition maximum three times per week for 12 weeks. Pharmacological doses of 600 mg of nandrolone per week yielded significant gains in total weight, lean body mass, body cell mass, and muscle size and strength. Increases in lean body mass and muscular strength were significantly augmented with weight training. There were no significant side effects and no increases in liver enzymes or blood lipids were observed.⁸

4. Gold J, et al. Safety and efficacy of nandrolone decanoate for treatment of wasting in patients with HIV infection. *AIDS* (1996) 10(7):745-752.

5. Bucher G, et al. A prospective study on the safety and effect of nandrolone decanoate in HIV-positive patients. XI International Conference on AIDS, Vancouver (1996) 11(1):26. Abstract No. Mo.B.423.

6. Schlumberger JM, et al. CD8+ lymphocyte counts and the risk of death in advanced HIV infection. *J of Family Practice* 1994;38,1(Jan):33-38.

7. Strawford, A, et al. Effects of nandrolone decanoate (ND) on nitrogen balance, metabolism, body composition and function in men with AIDS wasting syndrome (AWS). 2nd International Conference on Nutrition and HIV Infection, Cannes, France (1997):267.

8. Sattler FR, et al. Effects of pharmacological doses of nandrolone decanoate and progressive resistance training in immunodeficient patients infected with human immunodeficiency virus. *J Clin Endocrin Metab* (1999) 84(4):1268-1276.

Comparison of Studies of Anabolic Agents Used for HIV in the United States

Anabolic Agent Reference	Author/Year	Study Length Weeks	Number of Subjects	Exercise	Dose (mg) Frequency	Average Gain in Pounds	Cost per Month
Nandrolone 4	Gold 1996	16	17	Yes	100 mg every 2 weeks	6.6 – Wt	\$35
Nandrolone 5	Bucher 1996	12	73	No	100mg/week	5 – BCM	\$70
Testosterone Enanthate 9	Bhasin 1996 (non-HIV)	10	43	Yes	600 mg/week	13.42 – LBM	\$168
Nandrolone & Testosterone 3	Salvato 1997	12	20	No	Escalating-De-escalating 100-700 mg/wk	13 – Wt	\$224 Average
Nandrolone 7	Strawford 1997 2 phases	1st ph 3 wks 2 nd ph – 12 wks	18	No	1st - 195 mg/wk for 3 wks, then 2 nd - 200 mg every 2 wks	1st - 5.28 2 nd - 6.6 Total 11.88 LBM	\$115 Average
Winstrol 10	Berger 1993	10	1	No	6 mg/day	10 - Wt	\$72
Winstrol 10	Berger 1993	4	1	No	6 mg/day	3.5 – Wt	\$72
Nandrolone 8	Sattler 1999	12	30	Yes	600mg/week	11.44 LBM	\$288
Oxandrin 11	Poles 1997	8	21	No	20 mg/day	6.9 – BCM	\$900
Oxymetholone 12	Hengge 1996	30	30	No	150 mg/day	18 - Wt	\$1080
Serostim hGH 13	Schambelan 1996	12	178	No	6 mg/day	6.6 – LBM	\$6000

Some studies report only total weight (Wt), not lean body mass (LBM) or body cell mass (BCM). Given this, we present the limited available data. Note: BCM is the metabolically active tissue that includes muscle and organs like the heart, liver, and kidneys. LBM includes BCM, extracellular water, connective tissue and bone. Total weight includes LBM and fat.

9. Bhasin S, et al. The effect of supraphysiological doses of testosterone on muscle size and strength in normal men. *N Engl J Med* (1996) Jul 4; 335(1):1-7.
10. Berger J, et al. Effect of anabolic steroids on HIV-related wasting myopathy. *So Med J* (1993) August; 86(8):865-866.
11. Poles MA, et al. Oxandrolone as a treatment for AIDS-related weight loss and wasting. 4th Conference on Retroviruses and Opportunistic Infections (1997) Jan 22-26:193. Abstract No. 695.
12. Hengge UR, et al. Oxymetholone promotes weight gain in patients with advanced human immunodeficiency virus infection. *Brit J Nutr* (1996) 75:129-138.
13. Schambelan M, et al. Recombinant human growth hormone in patients with HIV-associated wasting: a randomized placebo-controlled trial. *Ann Intern Med* (1996) 125(11):873-882.