Informed Consent for Benzodiazepine Prescription

Please review the information listed here and initial each item when you have reviewed it with your provider and

understand each statement. This document provides important but not all concerns related to benzodiazepine use.	
I understand that I am being prescribed (provider to complete), which is in the clas	
of medications known as benzodiazepines (BZs).	
My provider is prescribing a BZ for the following condition(s):	
(provider to complete	
My provider has discussed available alternatives to BZs. (provider to list, including non-medication option	
BZs are meant for short-term (<2-4 weeks) ^{1,2,3,4,5} or intermittent use due to their long term-risks, including physical dependence. There are no studies showing convincing evidence of long-term benefit. ⁶	
FDA-approved indications for BZs include short-term relief of anxiety, 7 insomnia, 8 certain seizure conditions, 9,10 acute alcohol withdrawal, 11 procedural anesthesia, 12 and muscle spasms 13,14 (which is questioned 15,16,17). All other indications are considered "off-label" use.	
BZs have a "boxed" warning (the FDA's strongest warning) for risks when combined with opioids, 18 and the risks of abuse, addiction, physical dependence, and withdrawal. 19	
Common side effects ^{5,6} of BZ use include drowsiness, ^{20,21} dizziness, ^{20,22} balance problems, ^{22,23} confusion, ²⁴ muscle weakness, ²⁴ and depression. ²⁵ Serious risks include injuries/falls/broken bones, ^{26,27,28,29} car accidents, ³⁰ breathing problems ³¹ (especially in those with underlying lung problems), ^{32,33} suicidal ^{34,35} /violent thoughts, ^{36,37} overdose / overdose death ^{38,39,40} (especially when combined with opioids ⁴¹ or alcohol), ⁴² and death unrelated to overdose. ⁴³ Long term risks ^{5,6} (>2-4 weeks use) of BZ include memory loss, ^{21,44,45,46,47,48} osteoporosis, ²⁴ tolerance, ^{49,50} physical dependence, ^{5,6,51} withdrawal symptoms, ^{5,6} addiction, ^{6,52} increased healthcare costs, ²⁵ reduced quality of life, ^{53,54} and worsening of the original symptoms that were being treated. ^{55,56,57} For an extended list of adverse effects, see the FDA medication guide at https://www.fda.gov/drugs/drug-safety-and-availability/medication-guides and other sources. ^{5,6}	
When I take these medications regularly, I may develop tolerance ^{49,50} (needing a higher dose to have the same effect). I may also develop tolerance withdrawal ^{6,58,59} (withdrawal symptoms that happen even though the dose has not been lowered). Symptoms of tolerance or tolerance withdrawal may be mistaken for worsening of roriginal problem or a new medical condition. ^{5,6,60}	
When I take BZs regularly, physical dependence can develop in a matter of days , 61,62 even when taken exactly as prescribed. 63 This means my body needs the drug to function, and I will have withdrawal symptoms if the medication is stopped or the dose is reduced.	
Interdose withdrawal (withdrawal symptoms between doses) may occur, especially with short-acting BZs (e.g. Xanax, Ativan). ^{5,6,58,59} This may be corrected by switching to a longer-acting BZ (e.g. Valium). ^{5,6,64}	

I understand that BZs should never be stopped	abruptly, 5,6,65,66 as this can result in severe withdrawal
symptoms (e.g., psychosis,⁶⁷ seizures,^{61,68} and death). ⁶	^{8,69} It can also increase the risk of BZ injury syndrome. ^{6,47,70}
I understand that to stop using BZs, I will have t	o slowly reduce the dose of the medication, called
"tapering." ^{5,6,66,71,72} A BZ taper can last anywhere from	
	onvenient to taper and may need to be compounded or
	ezepine withdrawal can be extremely severe and disabling,
with symptoms lasting years in some cases, even with a	-
Symptoms of BZ withdrawal ^{5,6,73} include (but ar	e not limited to) extreme fear/anxiety, tremor, fast heart
rate, high blood pressure, agitation, perceptual disturb	ances, blurry vision and floaters, severe muscle spasm and
pain, involuntary twitching/movements, nerve pain, me	emory problems, loss of thinking ability, loss of ability to do
everyday tasks, extreme fatigue, muscle atrophy and w	reakness, weight gain or loss, hypersensitivity to light and
sound, suicidal thoughts, gastrointestinal problems (de	layed emptying of the stomach, food sensitivities, diarrhea,
constipation, and abdominal pain), tinnitus (ringing in t	the ears), head pressure/pain, blood sugar disturbances,
disrupted menstrual cycle and other hormone problem	s. For an extended list of symptoms see:
https://www.benzoinfo.com/benzodiazepine-withdrav	val-post-withdrawal-symptoms/
BZ use can cause changes in the nervous system	n, resulting in BZ injury syndrome (also called protracted
withdrawal). This occurs in 10-15% or more of patients	who discontinue long-term BZ use. ^{5,53} Symptoms may last
years, and in some cases damage may be permanent.	,47,60,73
I understand the above listed BZ adverse effect:	s can occur at "low doses," ⁷⁵ even when taken exactly as
prescribed by my provider, ⁶³ and can develop in the ab	sence of addiction or an "addictive personality." 6,76,77
For Women: Taking BZs while pregnant carries	a risk of miscarriage ⁷⁸ and can cause risk to the newborn
including breathing and breastfeeding problems, flacci	d muscles, and withdrawal syndrome. ^{79,80}
For Elderly: Patients over age 65 have an espec	ially high risk of side effects like falls, fractures, and
problems with thinking and memory, partly due to slov	ver metabolism of the drug from aging. 6,81,82,83,84,85,86
I understand I should not combine this medicat	ion with alcohol, Z-drugs (such as Ambien or Lunesta), other
	oing so can put me at risk of overdose and death due to
combined effects on breathing. 6,41,42,87,88 I agree to tell	my provider if new medications are added to my regimen.
Patient Name:	Patient DOB://
Patient Signature:	Date:/
Provider Signature:	Date:/



Authored by Benzodiazepine Information
Coalition <u>benzoinfo.com</u> and the Alliance for
Benzodiazepine Best Practices <u>benzoreform.org</u>.
Revised 06/19/2021. Please visit our websites
for more information and resources.

¹ Pottie K, Thompson W, Davies S, et al. Deprescribing benzodiazepine receptor agonists: evidence-based clinical practice guideline. *Canadian Fam Phys.* 2018;64(5):339-51. Article

- ³ Lader M. Benzodiazepine harm: how can it be reduced? *Br J Clin Pharmacol.* 2014;77(2):295-301. Article
- ⁴ Donoghue J, Lader M. Usage of benzodiazepines: a review. *Int J Psychiatry Clin Pract*. 2010;14(2):78-87. <u>Abstract</u>
- ⁵ Ashton H. The Ashton Manual: Benzodiazepines How They Work and How to Withdraw. 2002. Document
- ⁶ Peppin J, Raffa R, Pergolizzi J, Wright S [Eds.]. The Benzodiazepines Crisis: The Ramifications of an Overused Drug Class. New York, NY: Oxford University Press, 2020. <u>Link</u>
- ⁷ Bandelow B, Reitt M, Röver C, et al. Efficacy of treatments for anxiety disorders: a metaanalysis. *Int Clin Psychopharmacol.* 2015;30(4):183-92. <u>Abstract</u>
- ⁸ Sateia MJ, Buysse DJ, Krystal AD, et al. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med.* 2017;13(2):307-349. Abstract
- ⁹ Prasad M, Krishnan PR, Sequeira R, Al-Roomi K. Anticonvulsant therapy for status epilepticus. *Cochrane Database Syst Rev.* 2014;(9):CD003723. <u>Abstract</u>
- ¹⁰ National Institute for Health and Clinical Excellence: Guidance. The Epilepsies: The Diagnosis and Management of the Epilepsies in Adults and Children in Primary and Secondary Care: Pharmacological Update of Clinical Guideline 20. 2012. Document
- ¹¹ Amato L, Minozzi S, Vecchi S, Davoli M. Benzodiazepines for alcohol withdrawal. *Cochrane Database Syst Rev.* 2010;(3):CD005063. Abstract
- ¹² Messina AG, Wang M, Ward, MJ, et al. Anesthetic interventions for prevention of awareness during surgery. *Cochrane Database Syst Rev.* 2016;10(10):CD007272. <u>Article</u>
- ¹³ Groves L, Shellenberger MK, Davis CS. Tizanidine treatment of spasticity: a meta-analysis of controlled, double-blind, comparative studies with baclofen and diazepam. *Adv Ther.* 1998;15(4):241-51. Abstract
- ¹⁴ Greenberg DB. Strategic use of benzodiazepines in cancer patients. *Oncology (Williston Park)*. 1991;5(4):83-8. <u>Abstract</u>

² Lader MH. Limitations on the use of benzodiazepines in anxiety and insomnia: are they justified? *Eur Neuropsychopharmacol.* 1999;9(Suppl. 6):399-405. Abstract

¹⁵ Shakespeare DT, Boggild M, Young C. Anti-spasticity agents for multiple sclerosis. *Cochrane Database Syst Rev.* 2003;CD001332. <u>Abstract</u>

- ¹⁶ Abdel Shaheed C, Maher CG, Williams KA, McLachlan AJ. Efficacy and tolerability of muscle relaxants for low back pain: systematic review and meta-analysis. *Eur J Pain.* 2017;21(2):228-37. Abstract
- ¹⁷ Chou R, Deyo R, Friedly J, et al. Systemic pharmacologic therapies for low back pain: a systematic review for an American College of Physicians Clinical Practice Guideline. *Ann Int Med.* 2017;166(7):480-92. Abstract
- ¹⁸ FDA news release: FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from combined use. 31 Aug 2016. News Release on FDA Site
- ¹⁹ FDA news release: FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class. 23 Sep 2020. <u>News Release on FDA Site</u>
- ²⁰ Arbanas G, Arbanas D, Dujam K. Adverse effects of benzodiazepines in psychiatric outpatients. *Psychiatr Danub*. 2009;21(1):103-7. <u>Abstract</u>
- ²¹ Buffett-Jerrott SE, Stewart SH. Cognitive and sedative effects of benzodiazepine use. *Curr Pharm Des.* 2002;8(1):45-58. Abstract
- ²² Puustinen J, Nurimen J, Kukola M, et al. Associations between use of benzodiazepines or related drugs and health, physical abilities and cognitive function: a non-randomised clinical study in the elderly. *Drugs Aging*. 2007;24(12):1045-59. <u>Abstract</u>
- ²³ Mets MA, Volkerts ER, Olivier B, Verster JC. Effect of hypnotic drugs on body balance and standing steadiness. *Sleep Med Rev.* 2010;14(4):259-67. Abstract
- ²⁴ Longo LP, Johnson B. Addiction: Part I. Benzodiazepines side effects, abuse risk and alternatives. *Am Fam Physician*. 2000;61(7):2121-8. <u>Article</u>
- ²⁵ Kroll DS, Niece HR, Barsky AJ, Linder JA. Benzodiazepines are prescribed more frequently to patients already at risk for benzodiazepine-related adverse events in primary care. *J Gen Intern Med.* 2016;31:1027-34. Abstract
- ²⁶ Bakken MS, Engeland A, Engesæter LB, et al. Risk of hip fracture among older people using anxiolytic and hypnotic drugs: a nationwide prospective cohort study. *Eur J Clin Pharmacol*. 2014;70(7):873-80. Article
- ²⁷ French DD, Campbell R, Spehar A, Angaran DM. Benzodiazepines and injury: a risk adjusted model. *Pharmacoepidemiol Drug Saf.* 2005;14(1):17-24. Abstract
- ²⁸ Kowalski-McGraw M, Green-McKenzie J, Pandalai SP, Schulte PA. Characterizing the interrelationships of prescription opioid and benzodiazepine drugs with worker health and workplace hazards. *J Occup Environ Med.* 2017;59(11):1114-26. Abstract

²⁹ Pariente A, Dartigues JF, Benichou J, et al. Benzodiazepines and injurious falls in community dwelling elders. *Drugs Aging*. 2008;25(1):61-70. Abstract

- ³⁰ Dassanayake T, Michie P, Carter G, Jones A. Effects of benzodiazepines, antidepressants and opioids on driving: a systematic review and meta-analysis of epidemiological and experimental evidence. *Drug Saf.* 2011;34(2):125-56. Abstract
- ³¹ Horsfall JT, Sprague JE. The pharmacology and toxicology of the 'Holy Trinity'. *Basic Clin Pharmacol Toxicol.* 2017;120(2):115-9. Abstract
- ³² Nakafero G, Sanders RD, Nguyen-Van-Tam JS, Myles PR. Association between benzodiazepine use and exacerbations and mortality in patients with asthma: a matched case-control and survival analysis using the United Kingdom Clinical Practice Research Datalink. *Pharmacoepidemiol Drug Saf.* 2015; 24(8):793-802. <u>Abstract</u>
- ³³ Ekström MP, Bornefalk-Hermansson A, Abernethy AP, Currow DC. Safety of benzodiazepines and opioids in very severe respiratory disease: national prospective study. *BMJ*. 2014;348:g445. <u>Article</u>
- ³⁴ Dodds TJ. Prescribed benzodiazepines and suicide risk: a review of the literature. *Prim Care Companion CNS Disord.* 2017;19(2). <u>Abstract</u>
- ³⁵ Ghosh T, Bol K, Butler M, et al. Epidemiologic assessment of benzodiazepine exposure among suicide deaths in Colorado, 2015-2017. *BMC Public Health*. 2020;20:1149. Article
- ³⁶ Jones, KA, Nielsen S, Bruno R, et al. Benzodiazepines their role in aggression and why GPs should prescribe with caution. *Aust Fam Physician*. 2011;40(11):862-5. <u>Article</u>
- ³⁷ Saïas T, Gallarda T. Paradoxical aggressive reactions to benzodiazepine use: a review. *Encephale*. 2008;34(4):330-6. <u>Abstract</u>
- ³⁸ National Institute on Drug Abuse. National Drug Overdose Deaths Involving Benzodiazepines by Opioid Involvement, Number Among All Ages 1999-2017. Figure 8. January 2019. <u>Link</u>
- ³⁹ [No authors listed] CDC Vital signs: overdoses of prescription opioid pain relievers and other drugs among women United States, 1999-2010. *MMWR Morb Mortal Wkly Rep.* 2013;62(26):537-42. Article
- ⁴⁰ Bachhuber MA, Hennessy S, Cunningham CO, Starrels JL. Increasing benzodiazepine prescriptions and overdose mortality in the United States, 1996-2013. *Am J Pub Health*. 2016;106:686-8. Article
- ⁴¹ Chen LH, Hedegaard H, Warner M. Drug-poisoning deaths Involving opioid analgesics: United States, 1999-2011. *NCHS Data Brief.* 2014;(166):1-8. <u>Article</u>
- ⁴² White JM, Irvine RJ. Mechanisms of fatal opioid overdose. *Addiction*. 1999; 94(7):961-72. Abstract

⁴³ Belleville G. Mortality hazard associated with anxiolytic and hypnotic drug use in the national population health survey. *Can J Psychiatry*. 2010;55:558-67. <u>Abstract</u>

- ⁴⁴ Savić MM, Obradović DI, Ugresić ND, Bokonjić DR. Memory effects of benzodiazepines: memory stages and types versus binding-site subtypes. *Neural Plast.* 2005;12(4):289-98. <u>Article</u>
- ⁴⁵ Vermeeren A, Coenen AM. Effects of the use of hypnotics on cognition. *Prog Brain Res.* 2011;190:89-103. Abstract
- ⁴⁶ Beracochea D. Anterograde and retrograde effects of benzodiazepines on memory. *Sci World J.* 2006;6:1460-5. Article
- ⁴⁷ Barker MJ, Greenwood KM, Jackson M, Crowe SF. An evaluation of persisting cognitive effects after withdrawal from long-term benzodiazepine use. *J Int Neuropsychol Soc.* 2005;11(3):281-9. Abstract
- ⁴⁸ Barker MJ, Greenwood KM, Jackson M, Crowe SF. Cognitive effects of long-term benzodiazepine use: a meta-analysis. *CNS Drugs.* 2004;18(1):37-48. <u>Abstract</u>
- ⁴⁹ Soldatos CR, Dikeos DG, Whitehead A. Tolerance and rebound insomnia with rapidly eliminated hypnotics: a meta-analysis of sleep laboratory studies. *Int Clin Psychopharmacol.* 1999;14(5):287-303. Abstract
- ⁵⁰ Higgitt A, Fonagy P, Lader M. The natural history of tolerance to the benzodiazepines. *Psychol Med Monogr Suppl.* 1988;13:1-55. <u>Abstract</u>
- ⁵¹ Rickels K, Schweizer E, Case WG, Greenblatt DJ. Long-term therapeutic use of benzodiazepines. I. Effects of abrupt discontinuation. *Arch Gen Psychiatry*. 1990;47(10):899-907. <u>Abstract</u>
- ⁵² Blanco C, Han B, Jones CM, et al. Prevalence and correlates of benzodiazepine use, misuse, and use disorders among adults in the United States. *J Clin Psychiatry*. 2018;79(6):18m12174. Abstract
- ⁵³ Lugoboni F, Mirijello A, Mirijello A, et al. Quality of life in a cohort of high-dose benzodiazepine dependent patients. *Drug Alcohol Depend*. 2014;142:105-9. Abstract
- ⁵⁴ Tamburin S, Federico A, Faccini M, et al. Determinants of quality of life in high-dose benzodiazepine misusers. *Int J Environ Res Public Health*. 2017;14(1). pii: E38. Article
- ⁵⁵ Ashton H. Benzodiazepine withdrawal: outcome in 50 patients. *Br J Addict*. 1987;82:655-71. Article
- ⁵⁶ Cohen SI. Alcohol and benzodiazepines generate anxiety, panic and phobias. *J R Soc Med.* 1995;88(2):73-7. Article
- ⁵⁷ Smagula SF, Stone KL, Fabio A, Cauley JA. Risk factors for sleep disturbances in older adults: evidence from prospective studies. *Sleep Med Rev.* 2016;25:21-30. <u>Article</u>

⁵⁸ Hermann JB, Brotman AW, Rosenbaum JF. Rebound anxiety in panic disorder patients treated with shorter-acting benzodiazepines. *J Clin Psychiatry*, 1987;48 (suppl. 10):22-8. Abstract

- ⁵⁹ Kales A, Soldatos CR, Bixler EO, Kales JD. Early morning insomnia with rapidly eliminated benzodiazepines. *Science*. 1983;220(4592):95-7. Abstract
- ⁶⁰ Higgitt A, Fonagy P, Toone B, Shine P. The prolonged benzodiazepine withdrawal syndrome: anxiety or hysteria? *Acta Psychiatr Scand.* 1990;82(2):165-8. Abstract
- ⁶¹ Hu X. Benzodiazepine withdrawal seizures and management. *J Okla State Med Assoc.* 2011;104(2):62-5. Abstract
- ⁶² Ashton, H. Benzodiazepine withdrawal: an unfinished story. *Br Med J.* 1984;288:1135-40. Article
- ⁶³ Borg S, Blennow G, Sandberg P, et al. Benzodiazepine dependence and other long-term adverse effects a review. *Lakartidningen*. 1986;83(5):321-3, 326. <u>Link</u>
- ⁶⁴ Vgontzas AN, Kales A, Bixler EO. Benzodiazepine side effects: role of pharmacokinetics and pharmacodynamics. *Pharmacology*. 1995;51(4):205-23. <u>Abstract</u>
- ⁶⁵ Fluyau D, Revadigar N, Manobianco BE. Challenges of the pharmacological management of benzodiazepine withdrawal, dependence, and discontinuation. *Ther Adv Psychopharmacol*. 2018;8(5):147-68. Article
- ⁶⁶ Lader M, Tylee A, Donoghue J. Withdrawing benzodiazepines in primary care. *CNS Drugs*. 2009;23(1):19-34. Abstract
- ⁶⁷ Pétursson H. The benzodiazepine withdrawal syndrome. *Addiction*. 1994;89(11):1455-9. Abstract
- ⁶⁸ Martínez-Cano H, Vela-Bueno A, de Iceta M, et al. Benzodiazepine withdrawal syndrome seizures. *Pharmacopsychiatry*. 1995;28(6):257-62. <u>Abstract</u>
- ⁶⁹ Joughin N, Tata P, Collins M, et al. In-patient withdrawal from long-term benzodiazepine use. *Br J Addict.* 1991;86(4):449-55. Abstract
- ⁷⁰ Tata PR, Rollings J, Collins M, et al. Lack of cognitive recovery following withdrawal from long-term benzodiazepine use. *Psychol Med.* 1994;24(1):203-13. <u>Abstract</u>
- ⁷¹ Darker CD, Sweeney BP, Barry JM, et al. Psychosocial interventions for benzodiazepine harmful use, abuse or dependence. *Cochrane Database Syst Rev.* 2015;(5):CD009652. Abstract
- ⁷² Denis C, Fatséas M, Lavie E, Auriacombe M. Pharmacological interventions for benzodiazepine mono-dependence management in outpatient settings. *Cochrane Database Syst Rev.* 2006;(3):CD005194. Abstract

⁷³ Fixsen AM, Ridge D. Stories of hell and healing: internet users' construction of benzodiazepine distress and withdrawal. *Qual Health Res.* 2017;27(13):2030-41. <u>Abstract</u>

- ⁷⁵ Winokur A, Rickels K, Greenblatt DJ, Schatz NJ. Withdrawal reaction from long-term low dosage administration of diazepam. *Archives of General Psychiatry*, 1980;37:101-5. <u>Abstract</u>
- ⁷⁶ DuPont RL. A practical approach to benzodiazepine discontinuation. *J Psychiatr Res.* 1990;24 Suppl 2:81-90. Abstract
- ⁷⁷ Landry MJ, Smith DE, McDuff DR, Baughman OL. Benzodiazepine dependence and withdrawal: identification and medical management. *J Am Board Fam Pract.* 1992;5(2):167-75. Abstract
- ⁷⁸ Sheehy O, Zhao J-P, Bérard A. Association between incident exposure to benzodiazepines in early pregnancy and risk of spontaneous abortion. *JAMA Psych.* 2019;76(9):948-57. <u>Abstract</u>
- ⁷⁹ Kieviet N, Dolman KM, Honig A. The use of psychotropic medication during pregnancy: how about the newborn? *Neuropsychiatr Dis Treat.* 2013;9:1257-66. <u>Article</u>
- ⁸⁰ McElhatton PR. The effects of benzodiazepine use during pregnancy and lactation. *Reprod Toxicol.* 1994;8(6):461-75. <u>Abstract</u>
- ⁸¹ Bourin M. The problems with the use of benzodiazepines in elderly patients. *Encephale*. 2010;36(4):340-7. <u>Abstract</u>
- ⁸² American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc.* 2012;60(4):616-31. Abstract
- ⁸³ Gerlach LB, Wiechers IR, Maust DT. Prescription benzodiazepine use among older adults: a critical review. *Harv Rev Psychiatry*. 2018;26(5):264-73. Article
- ⁸⁴ Griffin CE, Kaye AM, Bueno FR, Kaye AD. Benzodiazepine pharmacology and central nervous system-mediated effects. *Ochsner J.* 2013;13(2):214-23. <u>Article</u>
- ⁸⁵ Carrière I, Mura T, Pérès K, et al. Elderly benzodiazepine users at increased risk of activity limitations: influence of chronicity, indications, and duration of action the three-city cohort. *Am J Geriatr Psychiatry*. 2015;23(8):840-51. <u>Abstract</u>
- ⁸⁶ Pariente A, Dartigues JF, Benichou J, et al. Benzodiazepines and injurious falls in community dwelling elders. *Drugs Aging*. 2008;25(1):61-70. <u>Abstract</u>
- ⁸⁷ Roehrs T, Roth T. Insomnia pharmacotherapy. *Neurotherapeutics*. 2012;9(4):728-38. <u>Article</u>
- ⁸⁸ Kaufmann CN, Spira AP, Alexander GC, et al. Emergency department visits involving benzodiazepines and non-benzodiazepine receptor agonists. *Am J Emerg Med*. 2017;35(10):1414-19. <u>Abstract</u>

⁷⁴ Inner Compass Initiative: The Withdrawal Project. Website